

IMPACT

International Medical Products Anti-Counterfeiting Taskforce

Facts | Activities | Documents
developed by the Assembly and the Working Groups
2006-2010

THE HANDBOOK

IMPACT

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Assembly and the Working Groups of**



2006 - 2010



The handbook contains a collection of documents prepared by the IMPACT Secretariat at the Italian Medicines Agency (AIFA), with financial support from AIFA.

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Agenzia Italiana del Farmaco, Via del Tritone 181, 00187 Roma

<http://www.agenziafarmaco.gov.it> | e-mail: d.digiorgio@aifa.gov.it

Editing Service

Tecniche Nuove, via Eritrea 21, 20157 Milano

Editorial Office: tel. 02.39090264, fax 02.39090255 | e-mail: libri@tecnichenuove.com

Sales: tel. 02.39090440, fax 02.39090373

<http://www.tecnichenuove.com> | e-mail: vendite-libri@tecnichenuove.com

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Compiling a book is a complex operation, which requires repeated checking of the text, the figures and the relations between these. Experience shows that it is practically impossible to publish a book free of errors. We will therefore be grateful those readers who will point out such errors.

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Editorial Staff: Domenico Di Giorgio (chief editor), Marta Gramazio (editing and graphics), Gianpaolo Derossi (graphical design), Emanuele Cesta, Marcello Chiavoni (proofreading), Gabriele Falcioni (CD-ROM development).

Cover: Gianpaolo Derossi

IMPACT Planning Group 2010: Dr Carissa Etienne (Chair: Assistant Director-General, Health Systems and Services, WHO), Dr Paul B. Orhii (Vice-Chair: Director-General, National Agency for Food and Drug Administration and Control, Nigeria), Ms Ruth Lee (Vice-Chair: Health Sciences Authority, Singapore), Dr Konstantin Keller (Chair Legislative and Regulatory Infrastructure Working group: Federal Ministry of Health, Germany), Dr Ilisa Bernstein (Chair Regulatory Implementation Working Group: Director, Pharmacy Affairs, Food and Drug Administration, USA), Ms Aline Plançon (Co-Chair Enforcement Working Group: INTERPOL), Mr Eric McIntosh (Co-Chair Enforcement Working Group: Therapeutic Goods Administration, Australia), Mr Eduardo Pisani (Chair Technology Working Group: Director General, International Federation of Pharmaceutical Manufacturers and Associations), Mr Ton Hoek (Chair Communication Working Group: Secretary-General, International Pharmaceutical Federation), Dr Sabine Kopp (until mid July 2010: Executive Secretariat ad interim, IMPACT, Quality Assurance & Safety: Medicines, World Health Organization), Dr. Domenico Di Giorgio (Rapporteur and Executive Secretariat ad interim, Italian Medicines Agency - AIFA), Agnes Mathieu (EU Commission).

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FOREWORD

OUR SUPPORT TO IMPACT

This handbook will discuss a topic that has been discussed at various ICDRA for the last 16 years: Counterfeit Medicines. As regulators, we know what we mean when we say counterfeit medicine. There may be small differences in our different national legislations but certainly we make no confusion between counterfeit medicines, substandard medicines and legitimate generic medicines. We know that counterfeit medicines are a global public health menace causing death, disability and injury. They destroy the credibility of health systems and waste precious human and financial resources. They are found in all countries, both developed and developing.

Responding to the growing public health crisis of counterfeit drugs, [and the call by the WHO Member countries at the ICDRA meeting in Madrid in February 2004](#), many stakeholders, including the World Health Organization, in February 2006 agreed to establish the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). The taskforce has been active in forging international collaboration to seek global solutions to this global challenge and in raising awareness of the dangers of counterfeit medical products.

In our recent ICDRA meetings in Seoul 2006, Bern 2008 and Singapore 2010, we reiterated our support to WHO for the establishment of IMPACT as the proper coordination mechanism to involve all parties that have a role to play in combating counterfeits.

However, this topic has become a controversial issue at the World Health Assembly where some participants have expressed concerns about the possibility that the fight against counterfeits may be used as a means to hinder the legitimate trade of generics. I respect all opinions, but I cannot see how fighting counterfeits can negatively affect generics. Generics constitute the majority of the medicines that are prescribed and consumed in our countries, they are essential to improve access to medicines and none of us can be accused or simply suspected to be trying to hinder generics.

I have the impression that this public health topic, that of counterfeit medicines, has become the victim of another debate, a debate on trade and intellectual property issues that is certainly legitimate but that should take place in other fora and among other experts and not affect our efforts aimed at protecting public health from the threat of counterfeits. This situation is hindering the work of WHO in this area but work has continued at the field level where national efforts have continued because the perception of the problem persists. No country is free from the problem of drug counterfeiting, both developing and developed countries alike.

Drug counterfeiting is a transnational criminal network and can only be dismantled through international collaboration. That is the reason we called for building an effective collaboration among stakeholders and a consensus opinion for the effective control of drug counterfeiting internationally.

[The establishment of IMPACT was an answer to our requests.](#)

Dr. Paul B. Orhii
Director General NAFDAC, Vice-Chair IMPACT

EDITOR'S NOTE

Counterfeit medical products are a major public health risk for all communities. The phenomenon has grown in recent years due to counterfeiting methods becoming more sophisticated and to the increasing amount of merchandise crossing borders.

Responding to the growing public health crisis of counterfeit drugs, in February 2006, many stakeholders, including the World Health Organization, launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). The taskforce, created in 2006, has been active in forging international collaboration to seek global solutions to this global challenge and in raising awareness of the dangers of counterfeit medical products.

At its core, IMPACT aims at building coordinated networks across and between countries in order to halt the production, trading and selling of fake medicines around the globe. IMPACT is a partnership comprised of all the major players in the fight against counterfeit medicines, including: drug and regulatory authorities, international organizations, non-governmental organizations, enforcement agencies and pharmaceutical manufacturers associations.

IMPACT provides the opportunity to discuss matters which fall within the Terms of Reference and, where appropriate, to formulate proposals and recommendations to be adopted through a consensus-based approach and made public. Such proposals and recommendations and working plans do not commit the participating governments, organisations, institutions, agencies and associations in any way, but constitute a reference for guidelines, official policy or other action, as appropriate, under the responsibility, and according to the prerogative, mandate and internal rules and procedures of each such participating governments, organisations, institutions, agencies and associations (both R&D based and generics).

This handbook resumes the activities and the history of the task-force, through a compilation of documents that were prepared between 2006 and 2010 as the "Declaration of Rome", the terms of reference, Q&A on the IMPACT activities, and a summary of working papers by each Working Group. No editing took place in order to maintain authenticity of previously adopted documents: this has caused an overlap of contents and redundant statements that were not eliminated.

This book is not a stand-alone document, nor a document that is intended to provide "full guidance", but an easy to access reference that provides an overview on draft and finalized guidance and actions by experts that have participated in the taskforce: this information is otherwise widely distributed at different locations (as for instance in the IMPACT website, <http://www.who.int/impact/en/>). The publication also includes a CD-ROM with the promotional videos and the graphic materials developed by IMPACT, and the files of the enclosed documents, for any suitable use: all documents are open to comments.

The officially endorsed documents are noted with a reference to the endorsement process: all the other documents in this handbook were developed by the IMPACT Secretariat, or by the Editorial Staff.



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WHAT'S IMPACT

1.1 IMPACT TERMS OF REFERENCE

As endorsed in the first IMPACT General Meeting[2006]

Mission: to promote and strengthen international collaboration to combat counterfeit medical products

1.1.1 Preamble

The need for greater international cooperation in combating counterfeit medical products has been recognized by the World Health Assembly in resolution WHA41.16 of 1988 and reiterated through resolutions WHA47.13 (1994), WHA52.19 (1999), and WHA57.14 (2004).

The establishment of an International Medical Products¹ Anti-Counterfeiting Taskforce, IMPACT, has been proposed by WHO² and endorsed by 160 participants at an international conference in Rome in February 2006, representing 57 national drug regulatory authorities, 7 international organizations, 12 international associations of patients, health professionals, pharmaceutical manufacturers and wholesalers. The Rome conference issued a set of principles and recommendations, enshrined in the Declaration of Rome³, calling for WHO to lead the establishment of IMPACT and set the conceptual framework for IMPACT's work.

On 5 April 2006, the 12th International Conference of Drug Regulatory Authorities in Seoul, Republic of Korea, welcomed the establishment of IMPACT and congratulated WHO on the establishment of IMPACT Secretariat.

The IMPACT is a voluntary grouping of governments, organisations, institutions, agencies and associations from developing and developed countries aimed at sharing expertise, identifying problems, seeking solutions, coordinating activities and working towards the common goal of fighting counterfeit medical products. IMPACT aims at ensuring appropriate regional representation, including in particular from developing countries.

1.1.2 Goals

Consistent with the above-mentioned World Health Assembly resolutions, IMPACT will aim to achieve the following main goals:

- improve collaboration among governments, organisations, institutions, agencies and associations engaged in combating counterfeit medical products at the national, regional and/or international level;
- in light of the global dimension of counterfeiting, raise awareness among international organisations and other stakeholders ;
- raise awareness among national and regional authorities and decision-makers with a view to calling for effective legislative measures in order to combat counterfeit medical products;

- establish mechanisms for the effective exchange of information and to provide assistance on specific issues pertaining to combating counterfeit medical products;
- develop technical and administrative tools to support the establishment or strengthening of international, regional and national strategies;
- encourage and facilitate coordination among different anti-counterfeiting initiatives.

1.1.3 IMPACT Objectives

The IMPACT Participants (as defined in 5.1 below) agree to collaborate in facilitating progress in the following areas:

- securing political will and commitment, adequate legal framework, and implementation commensurate to the impact of this type of counterfeiting on public health and providing the necessary tools for a coordinated and effective law enforcement;
- inter-sectoral coordination based on written procedures, clearly defined roles, adequate resources, and effective administrative and operational tools;
- creating an awareness about the severity of the problem among stakeholders and providing information to the health system and the public;
- development of technical competence and skills in required areas;
- development of appropriate mechanisms for ensuring vigilance and input from patients' groups, healthcare professionals, the medical product supply chain, other stakeholders and concerned parties (including technology and service providers), and the public.

1.1.4 Nature of IMPACT

IMPACT is a taskforce administered by WHO which provides the Participants the opportunity to discuss matters which fall within these Terms of Reference and, where appropriate, to formulate proposals and recommendations to be adopted through a consensus-based approach and made public. Such proposals and recommendations and working plans do not commit the participating governments, organisations, institutions, agencies and associations in any way, but constitute a reference for guidelines, official policy or other action, as appropriate, under the responsibility, and according to the prerogative, mandate and internal rules and procedures of each such participating governments, organisations, institutions, agencies and associations.

IMPACT is not a legal entity, and cannot therefore undertake any action, without the explicit agreement in writing of each participating governments, organisations, institutions, agencies and associations. In line herewith, IMPACT cannot be represented by individual participants at any other fora, unless all participating governments, organisations, institutions, agencies and associations have explicitly agreed to be represented in such a manner.

IMPACT Participants are encouraged to conduct activities which are consistent with the above-mentioned objectives under their own responsibility and according to their respective policies and principles. Fund-raising efforts of IMPACT Participants for their own activities will be subject to their own respective policies and principles.

1.1.5 IMPACT Collaborating Parties and Structure

1.1.5.1 Collaborating Parties

IMPACT is open to the following collaborating parties involved in combating counterfeit medical products:

Participants

- intergovernmental organizations and institutions, such as the World Health Organization; the European Commission; the Commonwealth Secretariat; the ASEAN Secretariat;
- governmental institutions and agencies;
- WHO Collaborating Centres competent in combating counterfeit medical products;
- international non-governmental organizations, with an active involvement in combating counterfeit medical products;
- international associations/umbrella organizations representing health professionals such as physicians, pharmacists, nurses, dentists;
- international associations/umbrella organizations representing patients and consumers;
- international associations/umbrella organizations representing manufacturers, the medical product supply chain, other stakeholders and concerned parties (including technology and service providers) of medical products.

Invited experts

The General Meeting and the Working Groups may invite individual experts, with outstanding experience and active internationally in the fight against counterfeit medical products, to participate in certain meetings of IMPACT, for the purpose of sharing information and/or advising the Participants on matters within the sphere of their competence. Invited experts will not, however, be considered as Participants.

Observers

The General Meeting and the Working Groups may furthermore invite governments, organisations, institutions, agencies and associations who do not meet the criteria for participation, but are involved in activities which are relevant to all or part of the goal and objectives of IMPACT to attend all or certain designated meetings of IMPACT, as observers.

Observers will not, however, be considered as Participants. Upon invitation of the Chairperson, they may, however, make a statement to present their views or positions on the issue under consideration.

1.1.5.2 General Meeting

IMPACT will be guided by the General Meeting. The Secretariat will develop guidance principles and a practical mechanism to ensure the effective operation of the General Meeting, the necessary geographical balance, a balanced representation of governmental and non-governmental participants, and the regular presence of relevant international organizations and representatives of patients' and health professionals' organizations. The General Meeting will review and decide on the final principles and criteria developed by the Secretariat. The list of participants to the

General Meeting as well as the proceedings will be publicly available. The General Meeting is expected to meet at least once a year.

The General Meeting will review the reports and proposals presented to it by the Planning Group [see 1.1.5.3] and, where appropriate, will recommend all or part of their content for endorsement by the respective IMPACT Participants, in light of the IMPACT goals and objectives. The responsibilities of the General Meeting will furthermore be to put forward proposals and make recommendations on matters within the IMPACT goal and objectives to IMPACT Participants.

The General Meeting will also be responsible for establishing ad hoc Working Groups to address and advise the General Meeting on issues relevant to IMPACT's goal and objectives, including the coordination of country focused initiatives. The General Meeting will perform its responsibilities through a consensus-based approach. The General Meeting will biennially elect a Chairperson and up to two Vice-Chairpersons to act for a two-year term. A Chairperson and Vice-Chairperson may not act for more than two consecutive terms without a one term hiatus. The General Meeting will annually elect one Rapporteur, to act for a one-year term.

The General Meeting will select a maximum of participants to participate in the Planning Group for 2-year terms, i.e. in addition to the Chairperson, Vice-Chairpersons and WHO, as ex-officio participants in the Planning Group.

1.1.5.3 Planning Group

The Planning Group shall be comprised of the Chairperson and the Vice-Chairpersons of the General Meeting, the Chairs of the Working Groups, the WHO Secretariat and other Participants appointed by the General Meeting. The responsibilities of the Planning Group will consist of the following:

- coordination of reports and proposals of relevant collaborating parties for review by the General Meeting;
- review and overall presentation of the output/reports of the Working Groups to the General Meeting;
- review and acceptance of applications for participation as experts or observers in IMPACT;
- identification of the need for invited experts (as described above) to support the achievement of the IMPACT objectives;
- identification of the need for the establishment of ad hoc Working Groups to address and advise IMPACT participants on specific issues relevant to the IMPACT goal and objectives (for confirmation by the General Meeting); and
- submission of proposals for nomination of candidates for Chairperson, Vice-Chairperson and Rapporteur to the General Meeting.

The Planning Group will operate by consensus, and will meet at least once a year.

1.1.5.4 Working Groups

As noted above, IMPACT may establish Working Groups to address and advise IMPACT Participants on specific issues relating to its goal and objectives, including the coordination of country focused initiatives. Working Groups will be lead by a Chairperson, selected by the General Meeting. The Chairperson must be a Participant. For the beginning, 5 Working Groups have been established as outlined at the end of this document.

Working Groups must ensure that Participants and Invited experts have the appropriate expertise. As long as this is

Each Working Group will develop proposed work plans, report and submit proposals to the General Meeting through the Planning Group.

1.1.5.5 Secretariat support for IMPACT

Subject to the availability of sufficient human and financial resources for this purpose, secretariat support for the IMPACT will be provided by WHO, through its Health Technology and Pharmaceuticals (HTP) Cluster at the Organization's headquarters in Geneva.

In this connection, WHO will, among other things,; (a) coordinate the organization of the meetings of the General Meeting, and of the Planning and Working Groups; (b) organise a central repository of information and documents relevant to IMPACT; (c) maintain a database of participants' activities which are completed, ongoing, or planned; (d) inform the participants of activities, ongoing, or planned; (e) prepare and distribute -- in consultation with the Planning Group -- draft agendas, meeting reports, progress reports, and overviews of implementation, etc; (f) create and manage an email list server and an IMPACT internet site (within the WHO domain); (g) receive and submit applications for participation, observership and liaison in IMPACT to the Planning Group and General Meeting, respectively, in accordance with the procedure described above; (h) receive and inform the General Meeting of notices of termination; and (i) take the necessary measures to ensure the confidentiality and protection of materials and information that are provided to WHO with the request to keep them protected from unauthorized access.

IMPACT documents and other output will be issued by WHO and will be disseminated with appropriate disclaimers, including that the content does not necessarily reflect the views or stated policy of the participating organizations, agencies and institutions (including WHO, providing the secretariat support for IMPACT), as well as a clarification of the nature of the proposals/recommendations put forward in such IMPACT documents, along the following lines:

" Consistent with the World Health Assembly Resolutions WHA41.16 (May 1988), WHA47.13 (May 1994), WHA52.19 (May 1999), and WHA57.14 (May 2004), and the Declaration of Rome (18 February 2006) IMPACT has been established to improve collaboration among international organizations, agencies, associations and institutions engaged in combating counterfeit medical products. The IMPACT participants have reached a consensus on the proposals and/or recommendations contained in this document. These proposals and/or recommendations may not, however, necessarily reflect the views or stated policy of the participating organizations, agencies or institutions, nor are they in any way binding on, nor do they commit, the organizations, agencies and institutions to whom they are addressed. These proposals and/or recommendations constitute a reference for guidelines, official policy or other action, as appropriate, under the responsibility and according to the prerogative, mandate and internal rules and procedures, of each such organization, agency, association or institution authority. The name of IMPACT and the role of any of its participants in it may not be used for, or in conjunction with, commercial purposes without the prior written permission of IMPACT participants or the participant in question, as the case may be."

1.1.5.6 Financing of, and fundraising for, the day to day operation of IMPACT (including the secretariat support)

Each Participant, observer, and invited expert will, in principle, be responsible for meeting its own expenses in relation to IMPACT (including, but not limited to, travel and subsistence for the attendance of General Meetings, Planning

Group meetings, Working Group meetings, country focused initiatives, etc). Subject to the availability of funds, WHO (as a provider of secretariat support) may, in consultation and agreement with the Chairperson, decide to support the participation of certain developing country Participants and/or of invited experts.

he secretariat support and related day to day operation of IMPACT will be financed by voluntary contributions from Participants. In addition, WHO may raise funds from other sources to support the work of IMPACT, in accordance with WHO's established policies and principles.

The acceptance by WHO of any contributions for IMPACT from the participating governments, organisations, institutions, agencies and associations, as well as from other sources will be subject to WHO's established policies and principles and to WHO's Financial Regulations and Rules, administrative procedures and practices. WHO will administer any such financial contributions through an allotment entitled "IMPACT". This allotment will be administered in accordance with WHO's Financial Regulations, Rules, administrative procedures and practices and will be subject to WHO's normal programme support costs. WHO will provide the participating organizations, agencies and institutions with an annual summary financial report, including information on contributions received for the IMPACT secretariat support and other activities.

1.1.5.7 Applications

Applications to become a Participant or Observer will be submitted to WHO for presentation to the Planning Group and the General Meeting, in accordance with the procedure described above.

1.1.5.8 Termination

Any participant, observer, and invited expert may decide to terminate its involvement in IMPACT by providing written notice to WHO as the IMPACT secretariat. WHO shall remove the organization, agency or institution or individual in question from the list of participants, observers, liaisons and co-opted experts, and inform the General Meeting accordingly. In addition, it should be noted that:

- the involvement of observers and invited experts extends only for as long as they are invited by the General Meeting; and that
- the involvement of any Participant shall terminate (on a voluntary basis or by consensus of the General Meeting), if and when this Participant ceases to meet the criteria set forth in the first paragraph of section 5.1 above or no longer subscribes to the goal and objectives of IMPACT as described above.

1.1.5.9 Amendments

These Terms of Reference may be modified by consensus at a General Meeting.

1.1.6 Notes

'The term 'medical products' encompasses medicines, vaccines, blood derivatives, other biologicals, diagnostics, medical devices and items, as well as their combinations and their components.

²The rationale for the establishment of an International Medical Products Anti-Counterfeiting Taskforce is provided in the document 'Combating Counterfeit Drugs: A Concept Paper for Effective International Collaboration'

<http://www.who.int/medicines/events/FINALBACKPAPER.pdf>

³<http://www.who.int/medicines/services/counterfeit/RomeDeclaration.pdf>

1.2 DECLARATION OF ROME

CONCLUSIONS AND RECOMMENDATIONS OF THE WHO INTERNATIONAL CONFERENCE ON COMBATING COUNTERFEIT MEDICINES DECLARATION OF ROME

18 February 2006

*The participants of the WHO International Conference
“Combating Counterfeit Drugs: Building Effective International Collaboration”,
gathered in Rome on 18 February 2006*

DECLARE

1. Counterfeiting medicines, including the entire range of activities from manufacturing to providing them to patients, is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems.
2. Because of its direct impact on health, counterfeiting medicines should be combated and punished accordingly.
3. Combating counterfeit medicines requires the coordinated effort of all the different public and private stakeholders that are affected and are competent for addressing the different aspects of the problem.
4. Counterfeiting medicines is widespread and has escalated to such an extent that effective coordination and cooperation at the international level are necessary for regional and national strategies to be more effective.
5. National, regional and international strategies aimed at combating counterfeit medicines should be based on:
 - a) political will, adequate legal framework, and implementation commensurate to the impact of this type of counterfeiting on public health and providing the necessary tools for a coordinated and effective law enforcement;
 - b) inter-sectoral coordination based on written procedures, clearly defined roles, adequate resources, and effective administrative and operational tools;
 - c) creating an awareness about the severity of the problem among all stakeholders and providing information to all levels of the health system and the public;
 - d) development of technical competence and skills in all required areas;
 - e) appropriate mechanisms for ensuring vigilance and input from healthcare professionals and the public.

6. *The WHO should lead the establishment of an International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of governmental, non-governmental and international institutions aimed at:*

- a) raising awareness among international organizations and other stakeholders at the international level in order to improve cooperation in combating counterfeit medicines, taking into account its global dimensions;*
- b) raising awareness among national authorities and decision-makers and calling for effective legislative measures in order to combat counterfeit medicines;*
- c) establishing effective exchange of information and providing assistance on specific issues that concern combating counterfeit medicines;*
- d) developing technical and administrative tools to support the establishment or strengthening of international, regional and national strategies;*
- e) encouraging coordination among different anti-counterfeiting initiatives.*

The IMPACT shall function on the basis of existing structures/institutions and will in the long term explore further mechanisms, including an international convention, for strengthening international action against counterfeit medicines.

1.3

WHO OPEN FORUM: IMPACT FREQUENTLY ASKED QUESTIONS

Document developed by the Planning Group for the “WHO Open Forum on International Medical Products Anti-Counterfeiting Taskforce” held in Geneva [26 March 2010]

http://www.who.int/mediacentre/events/meetings/2010/impact_20100326/en/

1.3.1 What is the background to WHO’s and Member States’ activities on counterfeit medicines?

World Health Assembly (WHA) resolution 41.16 (1988) requested “governments and pharmaceutical manufacturers to cooperate in the detection and prevention of the increasing incidence of the export or smuggling of falsely labelled, counterfeited or substandard pharmaceutical preparations” and requested the Director General “to initiate programmes for the prevention and detection of the export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations”. Responding to this resolution, a meeting, convened by WHO in Geneva, 1–3 April 1992, gathered experts representatives of governmental institutions of WHO Member States, the International Criminal Police Organization (INTERPOL), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the International Narcotics Control Board, the International Organization of Consumer Unions, the International Pharmaceutical Federation (FIP) and the World Customs Organization (WCO) (at the time known as Customs Cooperation Council).

WHA resolution 47.13 (1994) requested WHO to assist Member States in combating counterfeit drugs. This led to the creation of the WHO Project on Counterfeit Drugs (funded by the Government of Japan). Project staff conducted a several field studies on the occurrence of counterfeit drugs and oversaw drafting of the WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs, published in 1999. Additional funding was later received from the Governments of Australia and the UK for the support of specific activities.

In 2000, WHO, IFPMA, the European Generic medicines Association (EGA), and Pharmaciens Sans Frontières established a working group that presented a technical briefing during the WHA in 2001 and further disseminated the 1999 Guidelines.

1.3.2 What is the background to international collaboration on combating counterfeit medicines?

The problem of counterfeit drugs has been high on the agenda of the biennial International Conference of Drug Regulatory Authorities (ICDRA) since 1992. The recommendations emanating from these ICDRA meetings, led, inter alia, to the organization of an ad hoc ICDRA meeting on counterfeit medicines in Madrid, Spain in February 2004 in conjunction with the 11th ICDRA. The ad hoc meeting requested WHO, in collaboration with other stakeholders, to

draft an international convention on counterfeit drugs and to convene a meeting of drug regulatory authorities and other stakeholders, prior to the 12th ICDRA (April 2006), to review the draft.

Exploratory work showed, however, that there was no consensus among Member States on the appropriateness of or need for an international convention on counterfeit medicines. The main reasons given by Member States as to why a convention should not be developed at this time were that developing a convention would be extremely costly and time-demanding, and that a convention would have been justified if there were a need to establish limitations to the use of products/technologies that were legally available (e.g. narcotics, tobacco) but that this was not so in the case of counterfeit products which have no legal status anywhere.

1.3.3 When and how was IMPACT established?

WHO organized an international conference in Rome, 16-18 February 2006. The conference was attended by representatives of 57 national medicines regulatory authorities, seven international organizations, and 12 international associations of patients, health professionals, pharmaceutical manufacturers and wholesalers. The Declaration of Rome [see 1.2] was adopted by all 160 participants and stated that WHO should take the lead in establishing a taskforce, the purpose of which would be to lead international collaboration on combating counterfeit medicines. The Declaration also contained a set of principles and a conceptual framework for the task force's work aimed at ensuring that it takes account of public health interests.

The task force was named the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) and defined as a voluntary coalition of stakeholders that coordinates international activities aimed at combating counterfeit medical products for the purpose of protecting public health. Terms of reference were developed and a circular letter announcing the establishment of IMPACT was sent to all WHO Member States in September 2006.

The First IMPACT General Meeting took place in Bonn, Germany, in November 2006. It elected an IMPACT chair and vice-chairs, chairs of IMPACT's five working groups, and established a work plan for 2007. It also established a secretariat, to be hosted by WHO's anti-counterfeiting programme. However, the secretariat and governance are independent of WHO's structure [see 1.1 IMPACT terms of reference]. The IMPACT Secretariat is not independent WHO structure. It was provided by WHO EMP and its staff members, until its move to Italian Medicines Agency (AIFA). Examples of similar multi-stakeholder partnerships that exist under the auspices of WHO include the WHO Global Health Workforce Alliance and the WHO Partnership for Maternal, Newborn and Child Health.

1.3.4 Why is a global task-force to combat counterfeit medicines needed?

Counterfeit medical products put people's health and lives at risk. They are a major obstacle to improving global health. The medical product supply chain is global and counterfeiting threatens everyone. Even those who make and sell counterfeits risk consuming counterfeits made by others. IMPACT serves as the only global forum that can bring all concerned stakeholders together to discuss effective measures and exchange experience and expertise, particularly with respect to public health issues.

The broad spectrum of IMPACT stakeholders' mandates, roles, interests and experience reflect the recognition that combating the counterfeiting of medical products cannot be successfully achieved by the health sector alone. Rather, it is dependent on the coordinated efforts of and effective collaboration among a number of sectors, including the

health sector, enforcement, border control, justice (at all administrative levels) and the private sector. (The private sector includes manufacturers, importers, distributors, health professionals, media, patients/consumers and civil society.) The need for such extensive collaboration has long been recognized, as indicated by resolution WHA41.16 and in the aforementioned WHO guidelines. What is new is that a large number of distinct stakeholders now recognize the public health implications of counterfeiting of medical products and that WHO is the organization most suited to taking the lead role in the task force. Moreover, the recommendations, policy advice, and training materials developed by IMPACT are more likely to be effective at both national and regional levels than any such tools developed by individual organizations of countries.

1.3.5 Who participates in IMPACT?

According to its terms of reference, IMPACT is “open to the following collaborating parties involved in combating counterfeit medical products:

- intergovernmental organizations and institutions, such as the World Health Organization, the European Commission, the Commonwealth Secretariat, the ASEAN Secretariat
- governmental institutions and agencies;
- WHO Collaborating Centres competent in combating counterfeit medical products;
- international nongovernmental organizations, with an active involvement in combating counterfeit medical products;
- international associations/umbrella organizations representing health professionals such as physicians, pharmacists, nurses, dentists;
- international associations/umbrella organizations representing patients and consumers;
- international associations/umbrella organizations representing manufacturers, the medical product supply chain, other stakeholders and concerned parties (including technology and service providers) of medical products.”

All WHO's Member States are eligible to become collaborating parties in the task-force on a voluntary basis. Currently, the participants include nearly 40 Member States, representatives of the ASEAN Secretariat, the Commonwealth Secretariat, the Council of Europe, the European Commission, INTERPOL, the Organisation for Economic Co-operation and Development, WCO, the World Intellectual Property Organization, the World Trade Organization, and numerous nongovernmental organizations. In line with WHO's mandate, WHO's main role in the task force is to ensure its focus on patients' safety and public health. Several WHO departments and regional offices also actively contribute to combating counterfeit medicines. The IMPACT Secretariat ensures the necessary geographical balance among WHO Member States, as well as a balanced representation of governmental and nongovernmental participants, and of representatives of relevant international organizations, and patients' and health professionals' organizations.

1.3.6 How does the IMPACT partnership work?

IMPACT works through five technical working groups which address the areas where action is needed to combat the spread of counterfeit medicines. The five groups cover; legislative and regulatory infrastructure; regulatory implementation; enforcement; technology; and communication. A senior WHO staff member was elected chair of two general meetings and representatives from drug regulatory authorities in Nigeria and Singapore were elected as

vice-chairs of IMPACT. The main decision-making body is the General Meeting which convenes usually once a year and elects IMPACT officials for a two-year period. Activities are financed by voluntary contributions.

Diagram attached as Appendix.

IMPACT General meetings to date:

- General Meeting held in Bonn (Germany), 25–26 November 2006
- General Meeting held in Lisbon (Portugal), 10–14 December 2007
- General meeting held in Hammamet (Tunisia), 3–5 December 2008

1.3.7 How do WHO and IMPACT tackle the issue of conflict of interest?

To date, participation in task force meetings has not required any declaration of interests. This procedure is not normally required for meetings whose participants are clearly identified by their affiliation and who thus represent the views of their respective organizations.

Participation by Member States in the three general meetings held since 2006 has been good (from 28 to 36 countries), with more than half the participants being representatives of medicines regulatory authorities and other governmental institutions and agencies. Participants also included representatives of international organizations and international associations of patients, health professionals, pharmaceutical manufacturers and wholesalers.

IMPACT tracks who participates in its meetings, but for reasons of privacy and security, the names of those participants remain confidential. Only the details of affiliation and representation of official institutions and national authorities are disclosed.

1.3.8 How is IMPACT financed?

During 2006–2008 the collaborative work of the task force and its secretariat was funded (nearly US\$ 2.3 million) mainly by the European Commission and the Governments of Australia, Germany, Italy and the Netherlands (altogether 62%) and by WHO (30%). A special agreement has been signed between WHO and INTERPOL that seeks to strengthen the IMPACT secretariat. WHO's financing of, and fundraising for, the task force are governed by WHO's established policies and principles and subject to WHO's administrative procedures and practices.

The travel and subsistence costs of developing country participants and invited experts with respect to attendance at task force meetings have been covered by the task force. Not all funds spent for IMPACT related activities have been transferred to WHO. For some sources (e.g. The International Federation of Pharmaceutical Manufacturers & Associations), this may also include direct, in-kind contributions to the task force's meetings or activities. Additionally, numerous Member States and other stakeholders have made in-kind contributions to the task force: for example, by providing expertise, e.g. by sending their representatives to meetings of the task force, by collaborative effort in various working groups, or by organizing general meetings and/or working groups.

From 2009 onwards, major fundraising activities have been carried out by WHO. Currently, funds are available from Germany (US\$ 80,000) and The Netherlands (Euros 150,000), to support IMPACT's activities end of 2009 and early 2010.

1.3.9 How is IMPACT monitored?

IMPACT's planning group, which consists of the chairperson and the vice-chairpersons of the General Meeting, the chairs of the working groups, the IMPACT Secretariat and other participants appointed by the General Meeting, has a key role in monitoring the work of the task force.

In between the annual General Meetings of IMPACT, all activities are monitored by the planning group.

Specifically, the responsibilities of the planning group include:

- coordination of reports and proposals of relevant collaborating parties for review by the General Meeting;
- review and overall presentation of the output/reports of the working groups to the General Meeting;
- review and acceptance of applications for participation as experts or observers in IMPACT;
- identification of the need for invited experts (as described above) to support the achievement of the IMPACT objectives;
- identification of the need for the establishment of ad hoc working groups to address and advise IMPACT participants on specific issues relevant to the IMPACT goal and objectives (for confirmation by the General Meeting); and
- submission of proposals for nomination of candidates for chairperson, vice-chairperson and rapporteur to the General Meeting.

In mid 2009, WHO established a programme to coordinate its work to combat counterfeit medicines (the WHO anti-counterfeiting programme), including coordination with the members of IMPACT and providing it with secretariat functions.

1.3.10 How does IMPACT address the issues relating to intellectual property rights?

IMPACT combats both counterfeit-branded products, as well as counterfeit generic medical products. But IMPACT's primary focus is the protection of public health. Issues related to intellectual property protection are not within the scope of the task force.

Many WHO Member States do not have legal instruments specifically designed for combating the counterfeiting of medical products. Moreover, in some Member States the existing specific legal instruments are outdated and even inadequate. In these instances, competent authorities tend to make use of other, non-specific, legal instruments already available. The non-specific legal instruments most commonly used are those related to the protection of trade marks.

IMPACT promotes the use of legal instruments specifically designed to deal with the health consequences of counterfeiting of medical products.

1.3.11 Does IMPACT address the issue of substandard medicines?

No. However, it is recognized that certain measures for combating counterfeit medicines are similar to those that can be taken to reduce the incidence of substandard medicines. This is especially so in the areas of regulatory strengthening and monitoring of the distribution chain.

Issues relating to substandard medicines are addressed by the WHO Medicines Quality Assurance¹ and the WHO Regulatory Support² programmes.

1.3.12 What is the role of INTERPOL in the IMPACT Secretariat?

WHO has no mandate to deal with enforcement activities. But the criminal nature of counterfeit medical products requires close collaboration between NMRAs and enforcement authorities. Accordingly, an agreement was signed in January 2008 between WHO and INTERPOL, to enhance the collaboration between the two organizations.

In October 2008, during the INTERPOL's General Assembly, the INTERPOL member Countries adopted a resolution recognizing the necessity to support IMPACT and to improve international cooperation to combat counterfeit medical products.

In January 2010, INTERPOL created an independent unit, to support the IMPACT Secretariat, through development of coordinated enforcement activities.

1.3.13 Where can I find information about IMPACT?

IMPACT related information is available on the IMPACT web site (<http://www.who.int/impact>) currently hosted by WHO.

1.3.14 What has IMPACT achieved so far?

IMPACT's achievements are described in the document Overview of the IMPACT Working Group activities, which was prepared for the World Health Assembly (see http://apps.who.int/gb/e/e_who63.html and the IMPACT web site. (<http://www.who.int/impact>). All IMPACT outcomes are based on the voluntary contributions of IMPACT members, including national authorities, regulators, etc.

1.3.15 What is the difference between WHO and IMPACT Documents?

Different types of documents can come out of IMPACT's work, as follows:

- Working IMPACT documents - these are "living" documents, usually technical drafts, related to the objectives and initiatives of the five IMPACT working groups. They have no binding clauses for IMPACT members/participants nor for WHO Member States.
- Official IMPACT documents - these are usually technical documents that are of significant importance to the work of IMPACT in combating counterfeit medical products. Their final drafts are reviewed and endorsed by the IMPACT General meeting. If all partners endorse and agree the document during that meeting, it will be available for use by any interested party. The final version of these documents are treated as official IMPACT documents and posted on the IMPACT web site,
- WHO documents and WHO guidelines - these are of the highest level of WHO advice and recommendations available to Member States for their implementation. IMPACT documents could become a WHO document if they undergo WHO procedures including review by the relevant WHO Expert Committee processes. (WHO

documents generally undergo wide consultation with WHO Member States, experts and specialists (development and publication processes must adhere to WHO rules and procedures).

1.3.16 Will combating counterfeit medicines affect the availability of legitimate generic and legitimate branded medicines?

No. A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products.

Measures adopted to combat counterfeit medicines are aimed at products that have never been and would never be approved by a national authority, that have been manufactured outside regulatory controls by those who wish to remain unknown, and/or have been traded by individuals who conceal the true origin of their products.

All these situations are not related to the trade of legitimate generic and legitimate branded medicines.

Therefore, such measures should not result in affecting the availability in legitimate generic and legitimate branded medicines.

1.3.17 Notes

¹http://www.who.int/medicines/areas/quality_safety/quality_assurance/

²http://www.who.int/medicines/areas/quality_safety/regulation_legislation/

1.4 RECOMMENDATIONS FROM INTERNATIONAL CONFERENCES OF DRUG REGULATORY AUTHORITIES AND OTHER WHO REGIONAL MEETINGS

1.4.1 12th ICDRA Recommendations [Seoul, South Korea, 2006]

The 12th ICDRA congratulates WHO for the conference organized in Rome in February 2006 following-up on the recommendations of the 11th ICDRA and endorses the Declaration of Rome.

The 12th ICDRA welcomes the establishment of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) and congratulates WHO on establishment of the IMPACT Secretariat.

The 12th ICDRA expects IMPACT to:

- Work on the basis of terms of reference that should take into account the topics raised in the Rome Declaration and at the 12th ICDRA and should provide clear milestones and tangible results.
- Develop concrete and pragmatic proposals on how to improve national, regional and international strategies to combat counterfeit medicines.
- Analyse in particular how to improve the sharing of information on cases of counterfeit medicines taking into consideration existing systems, e.g. WHO Rapid Alert System.
- Take into consideration existing activities in order to use the synergies of such activities and avoid duplication of effort.
- The 12th ICDRA calls upon WHO to provide all necessary support to IMPACT via its Secretariat.
- It calls upon the national and regional authorities to fully support IMPACT by providing the necessary resources during its work and by implementing its recommendations.

1.4.2 13th ICDRA Recommendations [Bern, Switzerland, 2008]

- Medicines regulatory agencies (MRAs) should be more proactive in providing other NRAs and the general public with appropriate information on the scope of the problem of counterfeit medical products at the national level.
- MRAs should ensure that all concerned governmental institutions are aware of the scope of the problems related to counterfeit medical products and of the activities that are undertaken to address these at national and international level.
- MRAs should develop and adopt multipronged anti-counterfeiting strategies addressing at least: (a) ensuring proper regulatory oversight, (b) securing the supply chain, (c) increasing and applying penalties, (d) increasing public and health professional vigilance and awareness, (e) developing and applying effective

authentication and detection technologies, and (f) improving coordination with all concerned stakeholders at the national and international level.

- MRAs should clearly define the responsibilities of manufacturers and operators of the supply chain at all steps of the pharmaceutical supply system.
- In developing track and trace methodologies used to secure the supply chain, MRAs should take into account the need to ensure international compatibility in order to improve their effectiveness in tracking products that move across borders, whenever applicable.
- WHO and MRAs should promote the development of collaborative networks based on the principle of Single Points of Contact (SPOC).
- WHO should further assist MRAs to strengthen their capacity to detect and combat counterfeit medical products and to exchange information at the international level.
- WHO should further promote a harmonized definition of a counterfeit medical product that is based on the 1992 definition of counterfeit medicine, that focuses on the protection of public health, and takes into account the need to safeguard legitimate generic medicines.
- WHO should develop and implement initiatives aimed at disseminating awareness and triggering political will to combat counterfeit medical products.

1.4.3 IMPACT Technology Sub-Group meeting [Prague, Czech Republic, 2007 Meeting conclusions]

Members of the IMPACT technology group met in Prague to review information about innovative “track & trace”¹ and other technologies to tackle medicines’ counterfeiting. After a day session of presentations² from, and interaction with, 22 anti-counterfeiting technology providers, the group arrived at the following conclusions:

In general,

- There is probably no such thing as a “worldwide” applicable technology, and therefore different approaches are needed when considering counterfeit medicines in different parts of the world; members believe that a technology that succeeds in the developing world are likely work as well in a much more advanced region.
- There should be an examination of the international standardization of product coding (both type and organization of information) in order to improve communication while containing costs. On the other hand, standardization of covert technology approaches, such as application of special inks or similar approaches, is not likely at this stage to succeed, as such standardized markers would be easily be applied to fake medicines. Within the limits imposed by regulatory requirements, individual manufacturers should be free to develop, and should implement, anti-counterfeiting strategies that could be productspecific and include the possibility to choose whatever effective technologies are deemed optimal.
- The group recommended developing countries to prioritize strengthening their capacities to control the informal trade of medicines³, and focus special attention to compliance with Good Manufacturing Practices, Good Distribution Practices, and Good Pharmacy Practices as basic requisite to safeguard public health and prevent counterfeit medicines.
- Both developing and developed countries should implement technologies appropriated to their conditions and seek those that are compatible across borders.

Regarding specific technologies,

- Unique pack numbering, or mass serialization, is a preferred option. By incorporating a unique serial number along with a product identifier, such as the Global Trade Identification Number - GTIN⁴, plus lot and expiry data, one can facilitate both identification and authentication functions within one code.
- There are many different models for authentication, including:
 - Some aligned to end user verification (patient, doctor) via mobile phones, the Internet, etc.
 - Some focusing on the point of dispensing, with the pharmacist playing a vital role.

Many further options exist to authenticate products, by providing different layers of security, including:

- Security inks
- Invisible digital graphics and dots
- Surface fingerprinting
- Infrared invisible codes

These alternatives, however, add cost. Incremental costs need to be carefully compared with any benefits when analyzing their feasibility.

- There are currently multiple weaknesses in the use of Radio Frequency Identification (RFID) (e.g. cost, privacy concerns, complex logistics throughout the distribution chain) and there was consensus that full implementation is only foreseeable in a distant future; as a consequence, alternatives need to be sought for individual pack coding today.
- Technologies that are already available, and substantially cheaper, are strongly preferred where they could be feasibly applied, such as the 2D barcode being looked at closely in Europe.
- Many of the technologies reviewed require the existence of a centralized database with product ID/supply chain information. Ownership, storage and handling of the data, as well as cost sharing, are issues in the remit of national policies.
- Any technology adopted needs to be sustainable in the longer term. Sustainability is defined in terms of the five criteria for assessing technologies adopted by the IMPACT Technology Sub-Group: a) cost, b) scalability, c) specific country needs and situations, d) feasibility, e) regulatory implications
- Responsibility for authentication of medicines along the supply chain should end at the pharmacist or other final dispensing level. The burden of verifying authenticity should not be put on the patient.

Next steps for WHO/IMPACT:

- WHO/IMPACT should establish an ongoing dialogue between drug regulatory authorities, technology providers and other stakeholders in order to continually assess recent trends in anti-counterfeiting technologies.
- WHO/IMPACT will keep member states informed and, when appropriate, provide recommendations about new technologies available to fight counterfeit medical products.
- The WHO/IMPACT Planning Group will serve as a platform for interaction between the five different sub-groups, and help to exchange information on any overlapping policy areas.

1.4.4 Recommendations of WHO IMPACT Meeting Abuja [Nigeria, 2008]

Participants to the meeting reaffirmed the importance of having comprehensive legislation against counterfeit medicines established in each country. The WHO “Principles and Elements of Legislation . . .” are a useful tool for establishing national legislation and cooperation in the fight against counterfeit medicines.

The following improvements to the “Principles . . .” were suggested:

- Clarification of scope and definition
- Establish adequately resourced regulatory and enforcement institutions with appropriate powers and capacity delineated in legislation

In sanction section amend aggravating factors if perpetrator is misusing a position of trust.

To enhance implementation of the “Principles . . .” the following suggestions were made:

- Translate “Principles . . .” into more languages.
- Need to operationalize cooperation and information sharing within countries
- Need to operationalize cooperation and information sharing within regions and cross-border involving regional networks.

Existing African networks in the health sector provide an ideal platform to enhance and implement IMPACT’s “Principles . . .” and regulatory tools.

Build collaborative regional laboratory capacities in Africa.

To raise awareness by publicly communicating public health risks and harms, especially originating from illegal markets, enforcement actions and court decisions.

WHO should support regional initiatives to establish model legislation.

Participants suggest that importance of the fight to combat counterfeit medicines and progress achieved should be brought to the attention of the members of Executive Board for presentation at the World Health Assembly.

1.4.5 Recommendations from the Meeting “Using Technology to Combat Counterfeit Medical Products: Technology Developers Meet Manufacturers, Wholesalers and Regulators” [Singapore, 2008]

- A wide range of technologies is available and should be used for different levels of national capacity/infrastructure and purposes
- When developing and implementing anticounterfeiting strategies, countries should take into account a) a combination of technologies appropriate to their situation, b) the unique identification and integrity of the smallest packaging units, and, where feasible, c) the authentication of dosage forms.
- Regulatory authorities developing strategies for the use of technologies should consider the following criteria:
 - needs, risk & cost/benefit assessment, timeliness of response, efficiency, adaptability to local conditions, risk of affecting products’ safety & efficacy profile, ensure privacy & confidentiality of information, affordability & accessibility of the products, degree of burden on distribution system, impact on price, training of those involved, adequate resources and effective enforcement, and communication;

- Involvement of all stakeholders in the development of the strategy;
- Experience from other countries
- Need to periodically re-evaluate the effectiveness of the strategies adopted.
- Need to ensure interoperability within domestic supply chain and, where possible, internationally.

Regulatory authorities should consider the following needs:

- Authentication (including for forensic purposes), at least at the smallest packaging unit-level and, where feasible, at the dosage form-level:
 - screening through visual inspection and analytical techniques of different complexity depending on local priorities/objectives and available resources
 - cooperation from original manufacturers (e.g. specifications, advanced testing)
- Track and trace:
 - (e)-pedigree,
 - Tamper-proof, secure serialisation & database management/querying system
 - Global numbering system for the identification of items
 - Extend to dosage form-level where applicable & feasible.
- A global numbering system should be developed and gradually adopted depending on local priorities and conditions for track & trace purposes.
- National/regional anti-counterfeiting strategies should encompass all medical products, as appropriate.
- IMPACT should bring these recommendations to the attention of the WHA

1.4.6 Recommendations of the IMPACT Regional Conference [Kempton Park, South Africa, 2009]

The recommendations are the results of discussions among the four following groups:

Group A : **Angola – DRC – Kenya – Mauritius – Mozambique**

Group B : **Namibia – Seychelles – South Africa (I) - Uganda**

Group C : **Botswana, Lesotho, Swaziland and Tanzania**

Group D : **Nigeria – South Africa (II) - Zimbabwe – Zambia**

- Declare that counterfeit medical products should be considered as a major public health concern.
- Need for Common Legislation align with the IMPACT Legislative principles:
 - Have a common definition
 - Ensure effective and efficient prosecution.
- Encourage the creation of a National Taskforce:
 - Nomination and continuity of Single Points Of Contacts (SPOCs)
 - International affiliation with IMPACT;
- Outline the need for resources' mobilization for member countries and IMPACT
- Enhance information sharing:
 - Adopt WHO Rapid Alert System for the SADC region
 - Enhance the reporting of criminal cases to INTERPOL-IMPACT
 - Enhance the reporting of confirmed counterfeit products to IMPACT

- Improve the laboratory capacity through quality control laboratories accreditation and prequalification, and encourage inter-laboratories proficiency testing
- Enhance public awareness : media, web site, sharing expertise, education of consumers
- Enhance government and judicial awareness
- Affordable technologies to detect counterfeits should be used.

1.4.7 Zanzibar Declaration on Counterfeit Medical Products and Pharmaceutical Crime [2010]

We, the participants in the Zanzibar Meeting for Mamba III on counterfeit medical products and pharmaceutical crime, recognizing that:

Counterfeiting of medicines and pharmaceutical crime, including the entire range of activities from manufacturing to dispensing them to patients, is a vile and serious crime that puts human lives at risk and undermines the credibility of health system;

Counterfeiting of medical products and other related pharmaceutical offences are a serious crime that, because of its impact on health, should be combated and punished accordingly;

Coordinating efforts of all the different public and private stakeholders that are affected and are competent for addressing the different aspects of the problem is crucial;

Cooperation with International Organizations is important to implement regional and national enforcement anti-counterfeiting strategies;

Establishing an adequate and relevant legal basis - comprising criminal, administrative and civil frameworks - for enforcing and supervising compliance with laws and regulations by all concerned agencies is paramount;

This legal basis can be applied to all counterfeit medical products locally manufactured, imported or exported, in transit, in trans-shipment, in bonded warehouses, in free zones and in all situations related to international trade; Declare:

Our commitment to strengthen the fight against counterfeit medical products and other pharmaceutical crimes in the East African Community region by developing specific multi-disciplinary enforcement mechanisms and raising awareness;

Our willingness as Partner States to consider using the existing communication tools such as those from INTERPOL, World Customs Organization (WCO) and World Health Organization (WHO) to improve coordination and exchange of information amongst health, customs, police, judicial, and other enforcement authorities;

The necessity to harmonize health regulations and create an appropriate criminal law to combat counterfeit medical products - that can be branded or generic products - and pharmaceutical crime with the support of the East African Community (EAC) Secretariat;

The need to develop forensic investigations, to strengthen market surveillance and our willingness to leverage the laboratory capacity to detect and produce evidences related to counterfeit medical products;

Our disposition to foster international cooperation in combating counterfeit medical products, pharmaceutical crime and to coordinate with the concerned international organizations such as INTERPOL, World Customs Organization (WCO) World Health Organization (WHO),

Our support to the IMPACT multidisciplinary partnership and more particularly in matters of:

Producing tools and training materials based on the needs of all the stakeholders in the region;

*Supporting the various agencies in investigating counterfeit medical products and pharmaceutical crime;
Coordinating and encouraging activities and techniques for enforcement, implementation in the EAC region;*

1.4.8 14th ICDRA Recommendation [Singapore, 2010]

The 14th ICDRA reiterates the recommendations of the 12th and 13th ICDRA, congratulating WHO for its continued work in the anti-counterfeiting area.

Medicines Regulatory Authorities (MRAs) should develop and adopt multipronged anti-counterfeiting strategies addressing at least:

- Proper regulatory oversight
- Securing the supply chain
- Increasing and applying penalties
- Increasing public and health professional vigilance and awareness
- Developing and applying effective authentication and detection technologies and
- Improving coordination with all concerned stakeholders at the national and international level.

WHO should:

- Assist MRAs to strengthen their capacity to detect and combat counterfeit medical products and to exchange information at the international level.
- Promote a harmonized definition of a counterfeit medical product that focuses on the protection of public health, and takes into account the need to safeguard legitimate generic medicines

WHO and MRAs should promote the development of collaborative networks based on the principle of Single Points of Contact (SPOCs).

1.4.9 Notes

¹ *Track & Trace is the process of recording all the transactions of a shipment throughout the distribution chain*

² Available at <http://www.who.int/medicines/services/counterfeit/en/index.html>

³ Includes: street markets, smuggling, theft and other unregulated activities

⁴ <http://www.gtin.info/>

1.5 IMPACT STRUCTURE

Taken from the documents developed by the Planning Group for the “WHO Open Forum on International Medical Products Anti-Counterfeiting Taskforce” held in Geneva [26 March 2010] and from the IMPACT 2008 brochure

[<http://www.who.int/impact/FinalBrochureWHA2008a.pdf>]

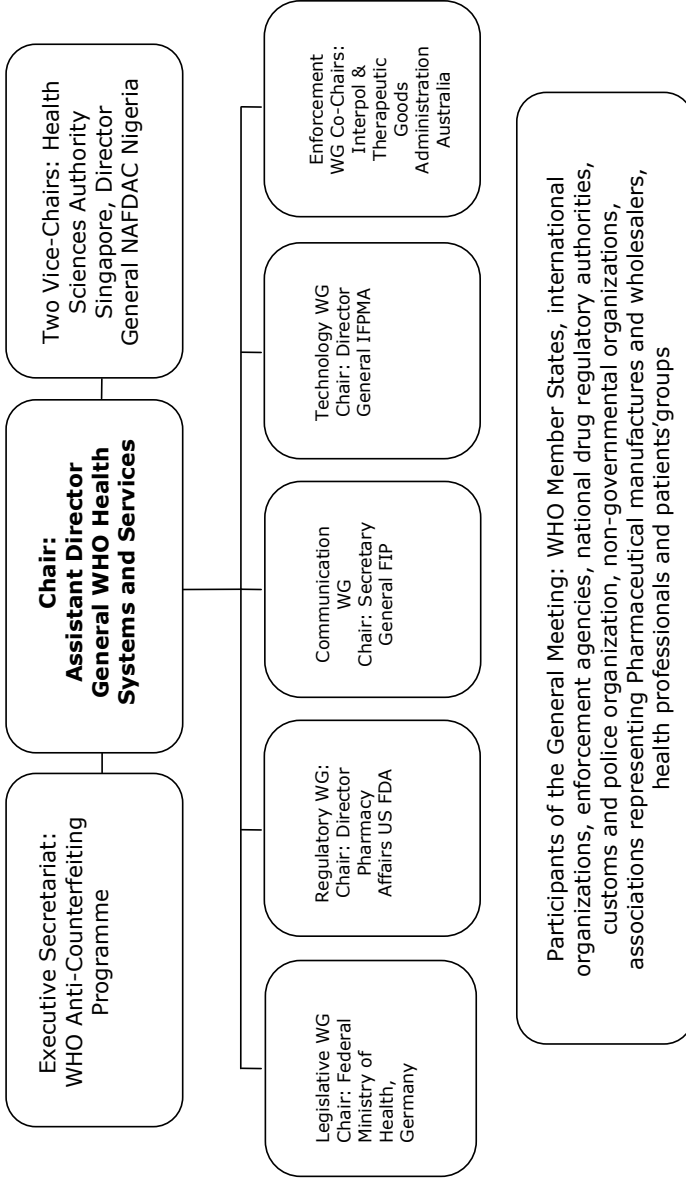
1.5.1 Participants

The World Health Organization spearheaded the creation of the WHO IMPACT coalition, which is supported by national medicines regulatory authorities of WHO Member States and a number of other stakeholders. These include: Interpol, Organisation for Economic Cooperation and Development, World Customs Organization, World Intellectual Property Organization, World Trade Organization, European Commission, Council of Europe, International Federation of Pharmaceutical Manufacturers and Associations, European Generic Medicines Association, World Self-Medication Industry, Asociación Latinoamericana de Industrias Farmacéuticas, Commonwealth Secretariat, ASEAN Secretariat, International Federation of Pharmaceutical Wholesalers, European Association of Pharmaceutical Full-line Wholesalers, International Pharmaceutical Federation, International Council of Nurses, World Medical Association, International Alliance of Patients’ Organizations, ReMed, Pharmaciens Sans Frontières, the United States Pharmacopeia, German Pharma Health Fund.

1.5.2 Structure

- IMPACT Chair: Assistant Director General of WHO Health Systems and Services
- Two Vice-Chairs: Health Sciences Authority Singapore, Director General NAFDAC Nigeria
- Executive Secretariat: WHO Anti-Counterfeiting Programme (2006-2010)
- Legislative WG Chair: Federal Ministry of Health, Germany
- Regulatory WG Chair: Director Pharmacy Affairs, FDA, USA
- Communications WG Chair: Secretary General FIP (International Pharmaceutical Federation)
- Technology WG Chair: Director General IFPMA (International Federation of Pharmaceutical Manufacturers & Associations)
- Enforcement WG Co-Chairs: INTERPOL and Therapeutic Goods Administration Australia
- Participants of the General Meeting: WHO Member States, international organizations, enforcement agencies, national drug regulatory authorities, customs and police organizations, non-governmental organizations, associations representing pharmaceutical manufacturers and wholesalers, health professionals and patients’ groups.

IMPACT's structure



1.6

AN OVERVIEW OF IMPACT WORKING GROUPS' DOCUMENTS AND ACTIVITIES

Document developed by the IMPACT Secretariat [2010]

Editorial note: we decided not to update the document with respect to the current status of the actions. Up to date, the actions under 1.6.1.1. and 1.6.2.6 were completed, whilst the ones under 1.6.1.2 are ongoing.

1.6.1 WG Legislation

1.6.1.1 Principles and elements for national legislation against Counterfeit Medical Products

The principles set out in this document focus on public and personal health implications in relation to counterfeit medical products that need to be appropriately addressed in legislation. Specific national and/or regional bodies of criminal, pharmaceutical, administrative and civil legislation may need to be enriched by the principles illustrated in this document, which are intended to complement or strengthen other legislation and not to replace it.

The document has been endorsed at IMPACT 2nd General Meeting, Lisbon, December 2007, was revised in the 3rd General Meeting in Tunis to include language that addresses a) counterfeit medical devices, and b) concerns raised by some WHO Member States at the 61st World Health Assembly in May 2008.

After editorial work, this draft will be posted on IMPACT web site to seek further comments and input from a broad constituency. It is envisaged that comments will be received until June 2009. Then a revised text consolidating all comments will be made available and discussed at a face-to face meeting of IMPACT's Legislative and Regulatory Infrastructure Working Group at a date to be determined.

1.6.1.2 A comparative study on existing legislation used to combat counterfeiting of medical products

The Max Planck Institute is leading this work to compare current forms of legal instruments in countries that can be used to sanction crimes relating to counterfeit medical products.

Result from preliminary analysis:

- no country uses subjective/mental elements in the national definition of counterfeit medical product
- many countries use the concept of "counterfeit-like offences", e.g. unauthorized or substandard medicines

Key considerations for future:

- clear definition needed;
- Impact of IMPACT definition on those countries;

- role of WHO documents in those countries;
- if subjective/mental elements are to be included in a footnote, the issue of recklessness / gross negligence/ careless behaviour needs to be added, because it is an element of the provisions in the text and important for clarifying the scope

1.6.1.3 Review of responsibilities of other stakeholders in the distribution chain. For example, Internet (and other) service providers

This is an analysis review of existing documents and activities, e.g.

- Council of Europe Convention on Cybercrime
- Council of Europe guidelines on distribution of medicines through internet
- Self-regulating standards by Industry (e.g. EBay) etc
- This is a work in progress: this initiative will be led by the Council of Europe with assistance from the WG where necessary.

1.6.2 WG Regulatory Infrastructure

1.6.2.1 A data collection tool to identify regulatory and legislative gaps in national situations

This assessment tool is designed to provide a unified approach of assessing the problem of counterfeit medicines in a particular country, sub-regional or regional setting. There are 7 parts to this tool: legislation, capacity of NMRAs, market control, documentation and reporting mechanism, awareness programmes, national and international Collaboration.

Process of development started April 2007. Discussed during the 2nd IMPACT General Meeting, December 2007 in Lisbon, Portugal. Reviewed by the Regulatory Implementation WG in Rome, 6-8 May 2008. Reported to National Drug Regulatory Authorities during 13th ICDRA meeting 16-19 September 2008.

Based on the field testing carried out this year in 8 countries (Burkina Faso, Cameroon, Mali, Morocco, Niger, Senegal, Tanzania and Uganda). A draft version should be ready for circulation for comments by May 2009.

1.6.2.2 Sampling strategy guidelines

This document highlights key issues and recommendations for developing an efficient suspect product sampling strategy. Elements of a procedure for collection and testing of samples for the purpose of detecting counterfeit medical products is also described.

The principles of this document were endorsed in the 3rd General Meeting with the intention to continue work on the draft document.

A new draft should be ready for circulation for comments by the next IMPACT assembly.

1.6.2.3 Guidelines for rapid response plan for national drug regulatory authority for signal of suspect counterfeit

National Medicines Regulatory Agencies (NMRA) must devise pro-active strategies to effectively fight and prevent counterfeit medical products. This document is intended to provide actions that may be followed by the NMRA in the event of suspect counterfeit medicines in the national distribution channels.

The first draft version has been written: it should be ready for circulation for comments by the next IMPACT assembly.

1.6.2.4 Developing Good Security Practices for printed packaging material for pharmaceutical products

Printed packaging materials are the communication interface between drug product quality and the patient. They have a very important role in drug safety as wholesalers, pharmacists, doctors and patients rely on it. Current legislation does not sufficiently take care that manipulations with printed packaging materials cannot happen. Therefore this document is proposed to serve as a new annex for the WHO GDP guidelines focusing on printed packaging materials.

A first draft has been written. Comments for next version include: *WCO should be approached in order to identify mechanisms to enable/alert customs authorities to 'do something' about ensuring that no trade of printed packaging materials of medical products is carried out without the obvious involvement of the appropriate right holders.

*Medical products manufacturing companies and, where applicable, distributors should be warned of the risks and, where applicable, a specific GMP requirement established regarding setting up a proper mechanism to ensure the safe management of printed packaging materials.

To further consider developing materials and strategies aimed at educating pharmacists, patients & other concerned parties regarding handling and safe disposal of packaging materials in order to prevent their reutilization. The second draft will be further circulated for comments in February 2009 taking into account the first round of recommendations received.

1.6.2.5 Guidance document for combating internet trade of counterfeit medical products (to be create/coordinate)

This document will focus on:

- IMPACT developed "positive" characteristics/principles for legitimate sale online;
- sharing experiences;
- certification system – existing criteria;
- clearinghouse of approved online pharmacies and where approved;
- include Portugal example regarding agreement with Google as advice for other DRA's to work with local Google;
- include discussion of freight companies/shippers and distribution channels and countermeasures.

The Communication WG has been also asked to develop consumer education campaigns regarding buying medical products online that can be used by DRA's and stakeholders in a variety of languages. A drafting team has been identified.

Issues to be debated:

- distinguish between medicines and medical devices;
- definition of “legitimate mail order/internet pharmacy business” and “illegitimate internet pharmacies”;
- standards/principles for internet pharmacies;
- endorsement programs - logos.

A first draft should be ready for circulation for comments by the next IMPACT assembly.

1.6.2.6 Counterfeit oriented revision of the WHO Good Distribution Guidelines (to be developed)

The WHO GDP document lays down guidelines for the distribution of pharmaceutical products. The main principles to secure the distribution chain established in this document may also be taken into account for medical devices. Recommendations are made where necessary to strengthen measures to combat infiltration of counterfeit medical products in distribution.

The first revised proposal to the WHO Expert Committee is now tabled for a second round of drafting. There is a need to coordinate the next necessary steps with the WHO Expert Committee.

1.6.2.7 Review national strategies regarding exporting pharmaceuticals an develop guiding principles for national regulatory authorities

This document should address two main areas: a) procedures to monitor/ regulate exportation b) mechanisms for international communication and exchange of information between relevant authorities.

This is a work in progress: a drafting team needs to be identified.

1.6.2.8 Develop guidance for ways to adapt current pharmacovigilance systems for counterfeit reporting

This requires contacting the relevant WHO unit and CIOMS to adapt, as necessary, CIOMS reporting form and some other aspects (obtaining samples of the suspected product remains a major issue).

This is a work in progress. There is need to identify volunteers to draft guidance for DRA's re: identifying signals within their pharmacovigilance system.

1.6.2.9 Update of 1999 WHO guidelines on measures to combat counterfeit medicines

All technical documents developed by IMPACT are reflecting the needs of Member States to effectively combat counterfeit medical products in a comprehensive manner. Conceptually, an IMPACT toolkit could be developed as a package of tools, including an updated WHO guidelines on measures used to combat counterfeit medical products.

This is a work in progress.

There is still work to be done to identify what needs to be done. The current plan is to envisage updating in 2010.

1.6.3 WG Enforcement

1.6.3.1 A guide to investigate counterfeit medical products and pharmaceutical crime

The intent of this guide is to provide investigate processes and techniques to countries developing investigative capacity to combat pharmaceutical crime. Particularly, identifying, investigating and prosecuting individuals and companies that import, manufacture, supply and export counterfeit medical products into, within and from countries. The guide has been prepared by members of the Permanent Forum on International Pharmaceutical Crime. The guide has also been developed to be as generic as possible on the basis that each country's medicine and medical product law and regulatory regime will differ.

Create an advanced version of the Crime Investigation Manual:

- intelligence gathering / Informants handling;
- money flow;
- Internet investigation / test purchase;
- Customs Risk Analysis;

1.6.3.2 A "Model for a Network of Single Points of Contact (SPOC)"

The aim of this initiative is to facilitate operational collaboration at the international level as well as to streamline collaboration among the different national institutions and other stakeholders involved in investigating and taking proper timely action when confronted with a case of counterfeit medical product. This builds upon the on the work done by the Council of Europe's Ad hoc Group on Counterfeit Medicines.

Three main operations were carried out in 2008: Operation Mamba (Uganda and Tanzania), Operation Storm (PR China, Myanmar, Thailand, Lao PDR, Cambodia, Vietnam, Singapore, Indonesia), and Operation Pangaea (on Internet sites).

IMPACT to set-up further operations in different regions.

1.6.3.3 IMPACT training courses

The guide to investigate counterfeit medical products and pharmaceutical crime, will be used in courses for the training of regulatory and enforcement officers.

In the countries involved in the IMPACT operations, systematic partnership: police-customs-regulatory authorities were forged. Trainings sessions were also conducted and translation of PFIPC Investigative guide manual into Khmer and Vietnamese language were done.

The plan is to organize another 8 to 10 training initiatives per year in the regions where operations take place. A focus on Western Africa : INTERPOL IPR Training Seminar and Workshop plus an ad hoc training seminar in Southern Africa.

1.6.4 WG Communication

1.6.4.1 IMPACT Communications Strategy

The communications strategy focuses on two main objectives: increasing awareness of the risk and promoting policy remedies proposed by IMPACT.

The overall vision of IMPACT is to fight for eradication of all counterfeit medicines. All counterfeit medicines will be eradicated from supply chains of the developed world and be reduced by two thirds in the developing world by 2020. A communications campaign is now required create awareness of the risk, support program policy objectives and increase commitment from those who can influence change.

Distinct target audiences have been identified. Specific key messages have been selected and tailored to each group for effective communications campaigning.

The strategy has been endorsed in the 3rd General Meeting and reiterated that this is to be considered a “living document” open to further expansion and periodic updates.

An internal WHO SharePoint portal has been initially setup but there is no active use and update of this tool.

The IMPACT website needs to be urgently updated.

A more effective internal communication protocol and structure has to be setup between the IMPACT Working Groups with a view to ensure consistent and regular information sharing so as to effectively disseminate timely and accurate information about counterfeit medicines and means to combat them to the international audience.

A full time communications officer needs to be established in the WHO IMPACT Secretariat.

1.6.4.2 Communications campaign focussing on patients

Patients and care-providers must make sure that they only buy from their legal outlets, such as pharmacies and appropriate trained personnel such as pharmacists and they should be educated about what is a counterfeit medicine.

The main key message is “Only get your medicines from known and reliable sources”.

The obtained results could be then summarized:

- the World Health Professions Alliance (WHPA) has developed print flyers for information to patients;
- the International Alliance of Patient Organizations (IAPO) has developed a Patient Safety Toolkit for patients' organizations which has a section on counterfeit medicines;
- initiated discussions with the Patients for Patient Safety programme in the WHO World Alliance on Patient Safety.

The goal is to further develop a multimedia campaign focusing on the personal and public health risks of counterfeit medical products to patients.

- collaborate further with WHO World Alliance on Patient Safety;
- a patient guideline on buying medical products and services over the Internet will be developed with WG Regulatory.

1.6.4.3 Communications campaign focussing on the general public

General Public must make sure that they only buy from their legal outlets, such as pharmacies and appropriate trained personnel such as pharmacists and they should be educated about what is a counterfeit medicine.

The concept of “World Anti-Counterfeiting Day” or “Safe Medicines Day” was proposed to be further explored with the IMPACT Planning Group and WHO.

Opportunities for a Public Service Announcement on combating counterfeit medical products project will be explored.

1.6.4.4 Communications campaign focussing on the media

Counterfeiting of medical products, including the entire range of activities from manufacturing to providing them to patients, is a vile and serious criminal offense that puts human lives at risk and undermines the credibility of health systems. The main key message is “Counterfeit medicines are a threat to personal and public health worldwide”.

IMPACT has been approached by a European TV programme (ARTE) to do a spot video on IMPACT.

5 IMPACT Factsheets have been developed, highlighting key messages relating to the 5 working areas of IMPACT and its stakeholders.

A major goal is to increase media activities on the international level, and where effective, at key national events. There is a need for an international ambassador or spokesperson for IMPACT, especially in expanding the TV, radio, newspaper and other media events of IMPACT.

1.6.4.5 Communications campaign focussing on health professionals

Health professionals need to consider counterfeit medicines as a reason for non-response or unexpected response in pharmacotherapy in the patients they care for. There is also an ethical call for health professionals to play a vigilant role in distribution and use of legitimate medical products themselves and when interacting with patients and their peers.

The World Health Professions Alliance (WHPA) has developed a counterfeit medicines toolkit for healthcare professionals. IMPACT has adopted these materials for its uses. A wider distribution plan for this toolkit needs to be in place.

A multimedia campaign will be further elaborated. Initial discussions have started with IMPACT and FIP. Ideally, this campaign should be launched at the 4th IMPACT General Meeting. This will be the focus for 2009.

1.6.4.6 Communications campaign focussing on the legitimate pharmaceutical supply chains

In order to successfully combat counterfeits a coordinated effort of all public and private stakeholders in the pharmaceutical supply chain is required where all share accountability; all bear responsibility; all invest resources.

An IMPACT global forum was organised in Singapore (Feb 2008), bringing together technology developers of anti-counterfeiting technologies and key impact stakeholders.

An industry consensus needs to be created amongst manufacturers and wholesalers on the level of individual responsibility required to prevent supply chain infiltration.

1.6.4.7 Communications campaign focussing on enforcement agencies and officers

Cooperation, collaboration and sharing of information beyond boundaries between Law Enforcement Agencies are a necessity for effective investigation and prosecution. The main message is “When existing laws are not adequate and rigorously enforced, crimes such as counterfeiting tend to perpetrate”.

Two short films were developed in 2008, one in Mali and one in Venezuela. Both films (3 minutes each) describe (in different contexts) an enforcement officer who loses a member of his family because of counterfeit medicines.

A short video has been developed in collaboration with Interpol with a focus on illustrating the dangers of the illicit supply chain and the role of IMPACT as a global taskforce to “win the race” in order to save lives.

Further collaborations with the work plan of the WG Enforcement needs to be explored. The role of pharmacists, pharmacy owners and pharmacy national associations can be further explored and integrated within the training and outreach projects of Interpol and WHO.

1.6.4.8 Communications campaign focussing on governments and other international NGOs and civil society groups

There is a need to raise the awareness of IMPACT among international organizations and national legislative, regulatory and enforcement authorities in order to strengthen international action against counterfeit medicines. The main message is “Medicines should not be traded as a commodity and when existing laws are not adequate and rigorously enforced, crimes such as counterfeiting tend to perpetrate”.

FIP organised a briefing at the 61st WHA May 2008, for IMPACT on the topic of the role of governments, NGOs and other international organizations in combating counterfeit medicines.

FIP will lead an initiative to constructively engage the most relevant NGOs and Civil Society groups in strengthening political commitments so as to bring about unified international actions to combat counterfeit medical products. Communications with the diplomatic missions based in Geneva will be conducted.

1.6.4.9 Prepare a proposal to hire an IMPACT communications officer

A dedicated communications officer is critical to support the above mentioned work plans and the various IMPACT communication campaigns.

An outline of key tasks for this portfolio has been developed. Funding efforts have begun.

WHO to investigate the possibility of supporting a full time communications officer at the WHO IMPACT Secretariat.

1.6.4.10 Revised WHO Rapid Alert System

A revised Rapid Alert System allowing member states to report cases and receive alerts when new cases are reported is being developed for a global audience, based on the RAS developed by the WHO Western Pacific Regional Office.

Specifications for a request for tender have been drafted based on the required purposes of a global RAS. To enable registered users to: a) report and store in a shared database cases of counterfeit medical products, b) receive alerts when selected reports are recorded in the system, c) browse the reports database, d) download selected reports, e) obtain contact details of other users of the system, f) provide and update user profile.

g) monitor use of the system and record activities.

WHO IMPACT Secretariat is to follow up the issue.

1.6.4.11 Revise and update IMPACT FAQ sheet

The existing FAQ draft needs to be reworked in accordance to the needs of its audience

- general FAQ on IMPACT is required;

- specific FAQ regarding the development of the “WHO definition” of a counterfeit medical product;
- translates some of the useful information of this document into an internal “Technical guidance for IMPACT stakeholders on communications and procedures”.

This is a work in progress: updated external IMPACT FAQ needs to be made available on the WHO IMPACT website. An internal IMPACT FAQ needs to be developed and shared among all IMPACT stakeholders and WG members

1.6.4.12 Develop network of national communications contact persons

This initiative aims to reach out and engage national communication contact persons who can support IMPACT communications in their countries. This is a work in progress: WHO IMPACT Secretariat needs to follow up.

1.6.5 WG Technology

1.6.5.1 Anti-counterfeit Technologies for the Protection of Medicines

This document assesses existing and new technologies to prevent, deter or help to detect counterfeit medicinal products taking into account: a) cost; b) scalability; c) specific country needs and situations; d) feasibility; e) regulatory implications. This is a “living” document of the WG and is continuously updated with regards to new trends and lessons learnt from implementation in countries. Last version updated as of Nov 2008. To continue monitoring and updating this document including basic principles of the tamper evident-outer pack closure system, electronic product ID and serialization and other latest technological developments.

1.6.5.2 Conduct series of workshops bringing regulators and technology developers together

These workshops mainly serve to better facilitate knowledge sharing and effective decision making regarding technology solutions. Two workshops have been conducted in Prague (2007) and Singapore (2008): the WG is considering plans for organising more similar workshops.

1.6.5.3 A review of existing and new field testing models

To review new developments in Minilab and Chinese Mobile labs, and extract lessons learnt. Start looking at experiences with new technologies, specific company arrangements, and assess effectiveness and implications. This is a work in progress: a note is to be produced and shared with WHO Member States and with Regulators.

1.6.5.4 Develop a technology supplement to the WG Enforcement guide to investigate counterfeit medical products and pharmaceutical crime

Review the Investigation Guide & SPOC (single point of contact) model with a view of proposing supplemental information that could help to fast track investigations for purposes of authentication. The supplement could be a set of critical elements to help investigators facilitate product authentication (ex. a checklist).

This is a work in progress: further update are expected.



2

**WORKING GROUP
ON LEGISLATIVE
AND REGULATORY
INFRASTRUCTURE**

2.1. OVERVIEW OF THE IMPACT WORKING GROUP ON LEGISLATIVE AND REGULATORY INFRASTRUCTURE

2.1.1 Preamble

In most countries, national legislation is often not equipped to deal with the extremely serious health consequences of counterfeit medical products and penalties for counterfeiters are too light to act as deterrents. Stronger legislation clearly identifying counterfeiting medical products as a crime will help to empower police, customs officials and the judiciary to better fight this crime.

2.1.2 Terms of reference

Currently chaired by Dr Konstantin Keller, from the Federal Ministry of Health, Germany The Working Group aims to:

- survey existing national and international legislation & requirements;
- assess gaps in existing national and international legislation & requirements on manufacturing, distribution, exportation, and importation;
- develop tools and elements for legislation;
- develop initiatives aimed at law-makers in order to promote adoption of new legislation ;
- requirements for the distribution system ;
- assess existing national best practices and develop model best practices.

2.1.3 Main achievements so far

- developed a draft IMPACT working document on “Principles and Elements for National Legislation against Counterfeit Medical Products”. The principles set out in this document focus on public and personal health implications in relation to counterfeit medical products that need to be appropriately addressed in legislation. National and/or regional legislation in the criminal, pharmaceutical, administrative and civil field may need to be enriched by the principles illustrated in this document, which are intended to complement or strengthen other legislation and not to replace it.

Status: currently under review by the WHO Expert Committee on Specifications of Pharmaceuticals and open for comments on the WHO website. The document was already used as a reference in the process of revision of the EU Directive 2001/83 and the draft Council of Europe Convention on counterfeiting of medical products and similar crimes involving threats public health (still ongoing). The need to further improve the document for better addressing the specific situation of medical device has been identified.

- Initiated a comparative study on existing legislation used to combat counterfeiting of medical products. The Max Planck Institute for international and foreign criminal law is leading this work to compare current forms of legal instruments in countries that can be used to sanction crimes relating to counterfeit medical products.

2.2

DRAFT PRINCIPLES AND ELEMENTS FOR PRINCIPLES AND ELEMENTS FOR NATIONAL LEGISLATION AGAINST COUNTERFEIT MEDICAL PRODUCTS

Draft as discussed at the Interregional Meeting of an ad-hoc Working Group on Medical Devices Bonn, Germany, 25-26 November 2008 and at the third IMPACT General Meeting in Hammamet, Tunisia, 3-5 December 2008

2.2.1 Introduction

The participants of the WHO international conference "Combating counterfeit drugs: building effective international collaboration", gathered in Rome on 18 February 2006, declared that:¹

- 1. Counterfeiting medicines, including the entire range of activities from manufacturing to providing them to patients, is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems.*
- 2. Because of its direct impact on health, counterfeiting medicines should be combated and punished accordingly.*
- 3. Combating counterfeit medicines requires the coordinated effort of all the different stakeholders that are affected and are competent for addressing the different aspects of the problem.*
- 4. Counterfeiting medicines is widespread and has escalated to such an extent that effective coordination and cooperation at the international level are necessary for regional and national strategies to be more effective.*
- 5. National, regional² and international strategies aimed at combating counterfeit medicines should be based on:*
 - a) political will, adequate legal framework and implementation commensurate to the impact of this type of counterfeiting on the health of individuals and on public health and providing the necessary tools for a coordinated and effective law enforcement;*
 - b) intersectoral coordination based on written procedures, clearly defined roles, adequate resources and effective administrative and operational tools;*
 - c) creating an awareness about the severity of the problem among all stakeholders and providing information to all levels of the health system and the public;*
 - d) development of technical competence and skills in all required areas;*
 - e) appropriate mechanisms for ensuring vigilance and input from healthcare professionals and the public."*

In addition, several international instruments, such as the International Covenant on Economic, Social and Cultural

Rights and the WHO Constitution, recognize the “right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.³

It is on the basis of the above principles that WHO and other stakeholders established the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) which aims at strengthening international collaboration among all the different stakeholders for the purpose of effectively combating counterfeit medical products.

IMPACT has established a secretariat within WHO and five working groups addressing these five areas: legislative and regulatory infrastructure; regulatory implementation; technology; enforcement; and communications.

Among the activities of the legislative and regulatory infrastructure working group, a project is being undertaken with the aim of developing guiding principles that national and regional institutions may use as reference for developing ad hoc legislation aimed at effectively combating counterfeit medical products within their jurisdiction.

Given the sophistication and global reach of many counterfeiting operations, the potential dangers to consumers, and the fact that counterfeiters operate outside of the medical product regulatory system, it is imperative that regulatory authorities, administrative and criminal law enforcement agencies, legitimate manufacturers and other concerned parties have at their disposal a comprehensive legal framework that: (i) subjects medical product counterfeiting activities to effective criminal sanctions, and deterrent civil and administrative remedies and penalties; (ii) adequately regulates and controls each link in the supply and distribution chain; (iii) empowers, directs and provides adequate technical, financial and human resources to medical product regulatory authorities, law enforcement authorities and customs to take effective and coordinated action, encompassing all aspects (including exports and online Internet activity); and (iv) educates stakeholders about the inherent dangers of counterfeit medical products.

IMPACT stakeholders have gathered experience and information on current national and international legislative instruments in different parts of the world. Although additional study is necessary to further improve our understanding, some lessons have been learned. Even if the situation appears to differ considerably (and, therefore, this list is not equally applicable to all WHO Member States), a number of key problems (others may exist) have been identified:

- a definition for counterfeit medical products is absent or inadequate;
- counterfeiting medical products is not considered per se to be a serious crime or even just a crime;
- where counterfeiting medical products is considered a crime, sanctions are sometimes much lighter than those applicable to counterfeiters of products that have no implications for health, such as T-shirts;
- sanctions are not linked to counterfeiting medical products per se, but to the proven fact that counterfeits have actually resulted in injuries or death;
- the responsibilities of those involved in the distribution system are not clearly defined;
- there are no provisions enabling effective coordination and exchange of information among different authorities and other stakeholders at the national, regional and international level;
- there are no provisions enabling different authorities to provide information to others (nationally, regionally and internationally) or to make legal use of the information obtained from others (nationally, regionally and internationally);
- there are no provisions addressing the problem of trade in packaging materials, especially labels, without the obvious involvement of the companies whose name appears on these materials;
- insufficient provisions concerning the confiscation and use of the assets, equipment and other materials used in conjunction with the manufacture, trade, transportation of counterfeit products.

A meeting of experts⁴ took place in Brussels on 12-13 July 2007 and prepared a preliminary document which was broadly circulated for comments. The revised version was discussed at a second, larger meeting of experts which took place in Lisbon on 10-11 December 2007. The result of this second meeting was discussed and finalized at the 2007 IMPACT General Meeting.

As suggested by the second general meeting an ad hoc expert group on medical devices was convened in December 2008 in order to clarify terms and requirements specific to medical devices. The ad hoc group proposed changes that were supported and clarified further by the third IMPACT General Meeting. The draft modifications specific to medical devices are presented here for comments and further improvement.

Based on the above considerations, this document is aimed at Member States that intend to establish, complement or update national/regional legislation or regulation against counterfeit medical products.

2.2.2 Scope

Counterfeit medical products need to be addressed through different bodies of legislation: on intellectual property protection and enforcement; on pharmaceutical and medical devices regulation and control; and on criminal law. All these bodies of legislation should be in place.

The principles set out in this document focus primarily on public and personal health implications in relation to counterfeit medical products (as defined below) that need to be appropriately addressed in legislation. As such these principles should be viewed in the context of a broader regulatory framework. Specific national and/or regional bodies of criminal, pharmaceutical, administrative, intellectual property and civil legislation may need to be enriched by or established on the basis of the principles illustrated in this document, which are intended to complement or strengthen other legislation and not to replace it.

On the basis of the above considerations the principles set out in this document do not address:

- infringement of aspects of intellectual property rights (IPR), including patent rights;
- parallel importation of original goods from a third country where they have been sold by or with the consent of the right-holder;
- illegal activities such as diversion or theft of medical products first placed on the market in compliance with the applicable regulatory requirements.

It is recognized that these principles may need to be further developed and constantly updated in order to take into account other international instruments and in order to better address emerging and specific issues, e.g. the complexity of Internet trade and medical devices. As medical devices are, in many countries, regulated differently from medicinal products and as in those countries the legal marketing of medical devices may not depend on an authorization, the term “authorization” or “authorized” is to be understood as “legally marketed” medical devices.

2.2.3 Terms used in this document

Recommendations from the Hammamet Meeting: “a common glossary of terms used by IMPACT needs to be established; no special glossaries”.

Broker: see Operator of the distribution chain

Counterfeit medical product: a medical product is counterfeit when there is a false representation (NOTE 1) in relation to its identity (NOTE 2) and/or source (NOTE 3). This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct components (NOTE 4) or with the wrong components, without active ingredients, with incorrect amounts of active ingredients or with fake packaging.

Violations or disputes concerning patents must not be confused with counterfeiting of medical products.

Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit.

Substandard batches of or quality defects or non-compliance with good manufacturing practices/ good distribution practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.

NOTE 1: Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behavior shall be considered during the legal procedures for the purpose of sanctions imposed.

NOTE 2: This includes any misleading statement with respect to name, composition, strength, or other elements.

NOTE 3: This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution.

NOTE 4: This refers to all components of a medical product.

Distributor: see Operator of the distribution chain.

Exporter: see Operator of the distribution chain.

Importer: see Operator of the distribution chain.

Manufacturer of medical devices: “Manufacturer” means any natural or legal person who designs and/or manufactures a medical device with the intention of making the finished medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by a third party(ies).

Manufacturer of medical products other than medical devices: any natural or legal person who:

- produces the medical products;
- engages in any part of the process of producing the medical products or of bringing the medical products to their final state. This includes any of the following: purchase of materials, processing, assembling, packaging, labelling, storage, sterilizing, testing and releasing for supply of the medical products or of any component or ingredient of the medical products as part of that process;
- has the medical products designed or manufactured (as defined above) by a third party;
- repackages or relabels medical products (as defined above).

Medical device: Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical or diagnostic purposes by in vitro means
- examination of specimens derived from the human body;

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Note 1: The definition of a device for in vitro examination includes, for example, reagents, calibrators, sample collection and storage devices, control materials and related instruments or apparatus. The information provided by such an in vitro diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions some in vitro diagnostic devices, including reagents and the like, may be covered by separate regulations.

Note 2: Products which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

- aids for disabled/handicapped people,
- devices for the treatment/diagnosis of diseases and injuries in animals,
- accessories for medical devices (see Note 3),
- disinfection substances,
- devices incorporating animal and human tissues which may meet the requirements of the above definition but are subject to different controls.

Note 3: Accessories intended specifically by manufacturers to be used together with a “parent” medical device to enable that medical device to achieve its intended purpose should be subject to the same Global Harmonization Task Force (GHTF) procedures as apply to the medical device itself. For example, an accessory will be classified as though it is a medical device in its own right. This may result in the accessory having a different classification to the “parent” device.

Note 4: Components to medical devices are generally controlled through the manufacturer’s quality management system and the conformity assessment procedures for the device. In some jurisdictions, components are included in the definition of a “medical device”.

Medical product: for the purpose of this document, medical products means medicines (including vaccines and other biologicals), medical devices (including diagnostics) and their accessories, active pharmaceutical ingre-

dients and excipients which may be used in health care delivery, self-medication and/or clinical research, as defined in national legislation.

Operator of the distribution chain: for the purpose of this document, this term encompasses any person or legal entity engaged in purchasing, selling, procuring, storing, distributing, dispensing, importing or exporting medical products, with the exception of dispensing/providing medical products to the end-users (see definition below for “retailer”).⁵ This refers, as applicable, to ownership, possession or control of the medical products in both national and international trade, including products in transit, transshipment, bonded warehouses, and “free trade zones”. Depending on national legislation, operators of the distribution chain will be referred to by different terms (e.g. distributor, wholesaler, full-line wholesaler, parallel trader, short-line wholesaler, broker, importer, exporter, sales representative, sales agent, etc.) reflecting specific activities and licensing or authorization requirements. For the purpose of this document all these activities are grouped under one definition because they should all be submitted to the same requirements and accountability in relation to counterfeit medical products.

Other operators involved: for the purpose of this document this term encompasses any person or legal entity engaged in advertising, providing platforms for trade, providing Internet services that facilitate trade and supply of medical products, and other communications services, transportation, storage, providing assistance in commercial and financial transactions, providing forwarding and logistics services. This refers, as applicable, to ownership, possession or control of the medical products in both national and international trade, including products in transit, transshipment, bonded warehouses, and “free trade zones”.

Retailer: for the purpose of this document this term encompasses any person or legal entity engaged in procuring and storing medical products in order to sell or dispense them to the end-users. This includes, but is not limited to, pharmacies, clinics, hospitals, doctors’ premises and retail outlets. This refers, as applicable, to ownership or possession of the medical products.

Sales agent: see Operator of the distribution chain

Sales representative: see Operator of the distribution chain

Wholesaler: see Operator of the distribution chain

2.2.4 Obligations of governmental institutions, manufactures, operators of the distribution chain, retailers and other operators

Combating counterfeit medical products is an obligation of all stakeholders, especially governments, and should be funded accordingly.

Sustained political will and strong commitment of governments are essential in order to develop and maintain a concerted effort to ensure the quality and safety of medical products and a decrease in the number of counterfeit medical products.

Establishment and supervision of compliance with obligations of manufacturers, operators of the distribution chain, retailers and other operators should be based on three main categories of approach:

- notification (by the regulated);
- authorization/licence (by the regulator);
- supervision/ inspection (directed by the regulator).

Manufacturers, operators of the distribution chain and retailers are expected to establish a quality assurance or quality management system. In addition, all parties should work together to fulfil their obligations in the fight against counterfeit medical products.

Government responsibilities include, among others, all the following:

- **1** establish an adequate legal basis (comprising criminal, administrative and civil frameworks), for imposing and supervising compliance with and enforcement of obligations by all concerned parties;
- **2** ensure that this legal basis can be applied to all medical products, including counterfeit medical products, in transit/transshipment, bonded warehouses, free zones and all situations of the international trade;
- **3** establish adequately resourced authorities charged with combating counterfeiting of medical products with appropriate investigative and enforcement powers enshrined in legislation;
- **4** in case a third-party assessment body is established, it should be made sure that the body is adequately designated and regular oversight established;
- **5** establish liability for Internet service providers and other operators who facilitate advertisement of or trade in counterfeit medical products;
- **6** regularly scrutinize and amend legislation as required;
- **7** regulate the manufacture, importation, exportation, distribution, supply, donation, offer for sale and sale of medical products, thereby ensuring that those who manufacture, import, export, distribute, supply and perform any transaction related to medical products, are in the possession of a specific licence,⁶ as applicable;
- **8** establish regulations aimed at fostering a safe, transparent and secure distribution system by establishing measures to ensure that medical products, as applicable, have a form of documentation that can be used to permit traceability of the products throughout the distribution channels from the manufacturer/importer to the retailer;
- **9** regulate the manufacture of active substances and of certain excipients entailing possible public health risks;
- **10** establish specific import (and export) procedures; this may include designation of a limited number of points of entry for imported medical products, as applicable, a measure which is particularly desirable in countries with limited human resources;
- **11** take measures to ensure that all medical products in the national distribution channels are licensed/ authorized as required by national legislation;
- **12** take measures to enforce effective compliance with documented procedures to ensure the appropriate destruction of counterfeit products; this includes the identification of operational and financial responsibilities;

- **13** ensure that licences/authorizations are revoked for poor or illegal performance as judged against established laws and regulations;
- **14** issue and renew licences on the basis of documented satisfactory compliance with existing laws and regulations;
- **15** require that medical products are suitably labelled and packaged according to their required specifications and licences/authorizations;
- **16** ensure that the conditions for importation of medical products, as applicable, are clearly specified and importation is undertaken only with the necessary import licences/authorizations issued by the national competent authority;
- **17** ensure that imported medical products, as applicable, are licensed/authorized in the country of manufacture or, where not, there are acceptable reasons for such non-authorization;
- **18** provide adequate resources for licensing and authorization activities concerning medical products as well as for related assessments and inspections;
- **19** provide adequate initial and in-service training for medical products control, customs and law enforcement personnel;
- **20** establish legal mechanisms to improve coordination and exchange of information among health, regulatory, police, customs and other enforcement officers/authorities at a national, regional and international level (especially the ability to provide and use the information exchanged in legal /regulatory action in each Member State);
- **21** ensure that imported medical products can be and are inspected at points of entry and that samples are collected and analysed as required by a national strategic plan;
- **22** permit investigators, under appropriate guidelines, to conduct effective investigations, e.g. under-cover operations, in which samples can be obtained anonymously;
- **23** perform effective controls and tests on medical products, as applicable, authorized for marketing in order to ascertain their quality and authenticity;
- **24** ensure that non-compliance with anti-counterfeiting laws and regulations attracts prosecution and severe penal sanctions and results in the confiscation, forfeiture and destruction of counterfeit medical products as well as equipment and other materials used in conjunction with their manufacture;
- **25** foster international cooperation in the control of medical products and enter into bilateral and multilateral agreements with other governments and with regional and international organizations such as WHO, Interpol, World Customs Organization, Council of Europe;
- **26** ensure that export controls/regulations take into account the following aspects:
 - a) same safety and performance standards (e.g. WHO Certification Scheme for pharmaceuticals, other type of official certification if applicable for other types of products; as applicable: marketing authorization, compliance with manufacturing practices requirements, appropriate product information, etc.) for exported as for domestic products,
 - b) clause for allowing importing countries to obtain products that satisfy their requirements although such products might not have marketing authorization in the exporting country,

- c) where applicable, clause mentioning remaining shelf-life to allow exportation providing a reasonable timeframe for use (e.g. residual shelf life should be at least 2/3 of shelf-life at lot release or six months if 2/3 of shelf-life is shorter than 6 months),⁷
- d) clause to regulate international trade of labels and packaging materials for medical products;
- **27** ensure that appropriate information on counterfeit medical products is provided to manufacturers, operators of the distribution chain, retailers, other operators and health professionals; information and related actions such as compliance and enforcement actions should be based on appropriate standards and permit a timely and appropriate risk assessment;
- **28** conduct awareness initiatives and ensure that appropriate information is provided to the public on counterfeit medical products in order to minimize the risk of exposure to such products;⁸
- **29** establish contact mechanisms, such as phone number/web site, to allow health professionals and the general public to report suspected cases of counterfeit medical products.

Responsibilities of manufacturers include, among others:

- **30** obligation to comply with applicable laws and regulations;
- **31** obligation to comply with official good practice guidelines (e.g. good manufacturing practices for medicinal products, good distribution practices⁹)
- **32** obligation to comply with applicable quality management systems requirement for medical devices;¹⁰
- **33** obligation to ensure supply of raw, starting and packaging materials from legitimate suppliers to manufacturers and ensure delivery of finished medical products from manufacturers to legitimate operators of the distribution chain, in accordance with applicable legislation, including, where appropriate, audits or appropriate certificates on the basis of risk assessment;
- **34** obligation to establish and maintain copies of records of transactions (including written contracts, where applicable) with suppliers, subcontractors and operators of the distribution chain;
- **35** obligation to document the origin of all materials used in the manufacture of authorized products in accordance with applicable GMP requirements;
- **36** obligation to have a process in place that would contribute to ensure that each batch received and shipped is accompanied by control reports (e.g. a certificate of analysis), as required by applicable legislation;
- **37** obligation to establish a quality assurance system which addresses (a) the manufacturer's response to reports of possible counterfeit medical products, (b) mandatory reporting of information to competent authorities and (c) work with competent authorities to trace, seize and destroy counterfeit product in compliance with applicable legislation;
- **38** obligation to document the appropriate disposal of expired or otherwise unusable products in a manufacturer's possession to prevent such products from re-entering the distribution chain;
- **39** obligation of manufacturers to cooperate with health, customs, police, other enforcement authorities and other stakeholders in the detection of counterfeit medical products, investigation of cases and the prosecution of those responsible for their manufacture or distribution **[see also 25, 26, 27]**.

Depending on product and circumstances manufacturers should undertake appropriate risk assessment to determine anti-counterfeit measures that should be taken to minimize product vulnerability to counterfeiting.

Manufacturers that use the Internet to sell and/or provide medical products should be submitted to the same requirements as both manufacturers and operators of the distribution chain **[see also form 59 to 63]**.

Responsibilities of operators of the distribution chain include, among others:

- **40** obligation to comply with applicable laws and regulations;
- **41** obligation to comply with official good practice guidelines (e.g. GDP¹¹) for medicinal products and applicable guidelines for active pharmaceutical ingredients (APIs) and excipients;
- **42** obligation to consider implementation of appropriate quality management systems for medical devices;
- **43** obligation to ensure supply of products from legitimate suppliers (manufacturers or operators of the distribution chain) and ensure delivery to legitimate operators of the distribution chain or retailers, in accordance with applicable legislation, including, where applicable, audits or appropriate certificates on the basis of a risk assessment;
- **44** obligation to establish and maintain copies of records of transactions (including written contracts) with suppliers, subcontractors and operators of the distribution chain;
- **45** obligation to accurately document the purchase and supply of all medical products, including returns from retailers;
- **46** obligation to ensure that each batch received and shipped is accompanied by appropriate documentation as required by national legislation;
- **47** obligation to establish a quality assurance system which addresses (a) the operator's response to suspicion or reports of possible counterfeit medical products, (b) mandatory reporting of information to competent authorities and (c) work with competent authorities to trace, seize and destroy counterfeit products in compliance with applicable legislation;
- **48** obligation of operators to cooperate with health, customs, police, other enforcement authorities and other stakeholders in the detection of counterfeit medical products, investigation of cases and the prosecution of those responsible for their manufacture or distribution **[see also 25, 26, 27]**;
- **49** obligation to document the appropriate disposal of expired or otherwise unusable products in the operator's possession to prevent such products from re-entering the distribution chain.

Operators should undertake appropriate risk assessment to determine anti-counterfeit measures that should be taken to minimize risks of acquiring or selling counterfeit medical products.

Internet site and mail order operators that offer for sale and/or provide medical products should be submitted to the same requirements as operators of the distribution chain or retailers, as applicable **[see also form 59 to 63]**.

Responsibilities of retailers

- **50** Obligation to comply with applicable laws and regulations.
- **51** Obligation to comply with official good practice guidelines (e.g. GDP, GPP¹²).
- **52** Obligation to establish and maintain records that allow for tracing medical devices beyond retailer level if and as required by applicable legislation.
- **53** Obligation to ensure supply from legitimate operators of the distribution chain.
- **54** Obligation to establish and keep copies of written contracts with suppliers, subcontractors and operators of the distribution chain.

- **55** Obligation to document the purchase and return of all medical products.
- **56** Obligation to establish an appropriate quality assurance system which addresses (a) the retailer's response to suspicion or reports of possible counterfeit medical products, (b) mandatory reporting of information to competent authorities and (c), work with competent authorities to trace, seize and destroy counterfeit product in compliance with applicable legislation.
- **57** Obligation of the retailer to cooperate with health, customs, police, other enforcement authorities and other stakeholders in the detection of counterfeit medical products investigation of cases and the prosecution of those responsible for their manufacture or distribution [see also 25, 26, 27].
- **58** Obligation to document the appropriate disposal of expired or otherwise unusable products to prevent them from entering into the distribution chain.

Depending on the national situation retailers may consider auditing distributors and requesting appropriate certificates. Retailers should undertake appropriate risk assessment to determine other anti-counterfeit measures that should be taken to minimize risks of acquiring counterfeit medical products.

Internet site and mail order operators that offer for sale and/or provide medical products should be submitted to the same requirements as operators of the distribution chain or retailers, as applicable [see also 59 to 63].

Responsibilities of other operators

- **59** Obligation to be aware of legal requirements regarding medical products and comply with applicable legislation.
- **60** Obligation to exert due diligence for ensuring business with legitimate business partners.
- **61** Obligation of operator to cooperate with health, customs, police, other enforcement authorities and other stakeholders in the detection of counterfeit medical products, investigation of cases and the prosecution of those responsible for their manufacture or distribution [see also 25, 26, 27].
- **62** Obligation to document any activity related to medical products.
- **63** Obligation to take the necessary actions in case operators have reasonable grounds to believe or notice has been given to them by the appropriate authorities of the fact that their services are being exploited for the trade/advertisement of counterfeit medical products.

Regional/international obligations

Due to the international nature of counterfeit medical products all governments are encouraged to establish a close and efficient cooperation in this area.

Governments, in line with existing international obligations, should make use of or establish legal mechanisms to permit:

- **64** regional/international exchange of information among health, regulatory, police, customs and other enforcement officers/authorities (especially the ability to provide and use the information exchanged in legal/regulatory action in each Member State); this includes all areas within Member States as well as free trade zones;
- **65** to facilitate cross-border joint operations among health, regulatory, police, customs and other enforcement officers/authorities; this includes all areas within Member States as well as free trade zones;

- **66** to use, to the widest extent possible, relevant regional/international instruments on international cooperation in criminal matters for the purposes of investigations, collection of evidence or proceedings concerning criminal offences related to counterfeit medical products;
- **67** to include criminal offences directly related to counterfeit medical products as extraditable offences;
- **68** to prosecute criminal offences directly related to counterfeit medical products by a country affected by such criminal offences even if committed abroad by or against a citizen of that country.¹³

2.2.5 Illegal acts

It is prohibited to:

- **1** manufacture, including performing any of the activities described above under “manufacturer”, a counterfeit medical product;
- **2** own, possess or control counterfeit medical products in transit, transshipment, free trade zones, bonded warehouses and other situations of international commerce;
- **3** introduce into the distribution chain any counterfeit medical product through any means including but not limited to selling, delivering, distributing, importing, exporting, donating or otherwise supplying others with a counterfeit medical product, or storing it;
- **4** own, possess or control counterfeit medical products that are likely to enter the distribution chain;
- **5** design, produce, print, sell, deliver, distribute, import, export, donate or otherwise supply others with any packaging material, including labels, intended for a counterfeit medical product;
- **6** manufacture, transport, or distribute any equipment, materials, components (including genuine ones) or documentation used in the production or to accompany the distribution of counterfeit medical products with the knowledge of or being reckless to the fact that they be used for such purposes;
- **7** to provide services such as online services, electronic sale platforms, electronic payments or transport to persons or legal entities when such service providers have reasonable grounds to believe or notice has been given to them by the appropriate authorities that such persons or legal entities are using such services to engage in any of the offences described above;
- **8** conspire to commit, attempt to commit, aid and abet, counsel or facilitate or incite to commit any of the offences set forth in these provisions.

These acts should be considered illegal acts regardless of the value or volume involved.

2.2.6 Sanctions

Given that counterfeiting of medical products per se represents a serious threat to individual health and jeopardizes health care systems, governments should take all necessary measures to effectively deter the illegal acts described above (section 4), including introducing severe criminal sanctions against its perpetrators regardless of evidence of actual harm caused to others.

The illegal acts described above (section 4) should be considered a criminal offence even if committed by negligence.

These sanctions should:

- reflect the gravity of the respective offences, especially according to the presence and level of guilt,

- be equivalent to those provided by national legislation for other serious crimes, such as the manufacture or commercialization of dangerous substances or substances harmful to human health or drug trafficking, and
- include, where applicable constitutions or other instruments permit, mandatory prison sentences.

Quality defects or GMP/GDP failures in authorized medical products should not be confused with counterfeiting. The specific circumstances and facts (e.g. previous record of persons involved, availability of proper documentation regarding manufacture or trade, etc.) will permit to identify cases where offences are the result of a manufacturing or trade accident.

When sentencing the following aggravating circumstances should also be taken into consideration, with the understanding that counterfeiting medical products is a serious crime per se regardless of evidence of harm actually caused:

- **1** death or serious injury to persons affected;
- **2** effect upon the health of a large number of persons;
- **3** risk of endangering the health of a large number of persons;
- **4** risk of death or serious injury to persons affected;
- **5** acquisition of considerable pecuniary gain;
- **6** perpetrator is an authorized operator (manufacturer, retailer, other);
- **7** perpetrator is misusing a position of trust, e.g. a health professional;
- **8** repeated offence;
- **9** organized crime;
- **10** exposure of a large number of persons to ineffective diagnostics.

In addition, other offences that present themselves in conjunction with counterfeit medical products may also be pursued and penalized under other applicable criminal, civil and/or administrative legislation.

In order to effectively combat counterfeiting and ensure enforcement of anti-counterfeiting laws, certain procedural rules and provisions might need to be established or enhanced, including provisions to ensure transparency of processes and decisions, while maintaining confidentiality as necessary.

2.2.7 Nature of sanctions

In order to effectively combat counterfeiting of medical products the sanctions described below should be available without prejudice to those additional remedies and/or sanctions which are available under relevant criminal, civil or administrative legislation:¹⁴

- **1** custodial sentences;
- **2** fines;
- **3** confiscation of assets, including forfeiture of illegal proceeds;
- **4** confiscation of instruments, equipment and materials used to commit the crime;
- **5** total or partial closure, on a temporary or permanent basis, of the establishment(s) involved in the commission of the offence;
- **6** permanent or temporary prohibition to engage in medical product-related activities;
- **7** destruction of the counterfeit goods involved in the offences and recovery of the related costs;
- **8** ban on the access to public assistance or subsidies;
- **9** placing the operation under judicial supervision;

- **10** judicial order to close or wind up the operation and related activities;
- **11** indemnification of affected/damaged parties (including inter alia affected patients, affected operators and manufacturers of genuine products);
- **12** publication of judicial decisions (including dissemination of information to international organizations and to national competent authorities of other countries);
- **13** withdrawal of licences.

Without prejudice to other compensation mechanisms and to the ability of concerned parties to seek redress of injuries or damages that may have been suffered by patients, health professionals, manufacturers or operators of the distribution chain and their licensees, money derived from confiscation of assets should contribute to compensating the victims and supplement the financing of anti-counterfeit medical product operations by the appropriate authorities.

2.2.8 Notes

¹The full text of the Declaration of Rome can be found at <http://www.who.int/medicines/services/counterfeit/RomeDeclaration.pdf>; [see 1.2] the text presented here has been slightly updated for the purposes of clarity and consistency with the text of this document. Although the original text of the Declaration refers to medicines, the subsequent establishment of IMPACT expanded the scope to include all medical products.

²Throughout this document, the term “regional” refers to any regional or subregional gathering of countries (e.g. MERCOSUR, SADC, ASEAN, GCC, EU, etc.).

³WHO Constitution.

⁴See Annex 1 for a list of participants.

⁵End-users can be patients, consumers or professionals who directly use the products on patients/consumers.

⁶Note: Specific WHO documents and, where available, applicable national regulations provide more details on good manufacturing and good distribution practices.

⁷WHO guidelines for drug donations: <http://www.who.int/medicinedocs/collect/edmweb/pdf/whozip52e/whozip52e.pdf>.

⁸Specific model materials and advice are developed by IMPACT’s Working Group on Communications.

⁹Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Volume 2, Second updated edition. Good manufacturing practices and inspection. Geneva, World Health Organization, 2007 <http://www.who.int/medicinedocs/collect/edmweb/pdf/s4900e/s4900e.pdf>.

¹⁰For example, ISO Standard 13485.

¹¹Reference to WHO GMP, GDP and GPP guidelines http://www.who.int/medicines/areas/quality_safety/quality_assurance/en/index.html

¹²Reference to WHO GDP and GPP guidelines http://www.who.int/medicines/areas/quality_safety/quality_assurance/en/index.html

¹³*In proceedings involving the infringement of (registered) intellectual property rights, these considerations may be complemented by relevant principles on exclusive jurisdiction, especially over validity matters.*

¹⁴*This list is not exhaustive.*

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3

**WORKING GROUP ON
COMMUNICATION**

3.1 OVERVIEW OF THE IMPACT WORKING GROUP ON COMMUNICATION

3.1.1 Preamble

The infiltration and sale of counterfeit medicines in the legitimate supply chain can cause death and misery to tens of thousands of patients around the world.

Failure to act to prevent this criminal activity would be a fundamental breach of the trust placed in public health structures by patients. Any effective solution must drive immediate change, be effective in the long term and receive the support and active engagement and collaboration of all stakeholders managing the medicines supply chain.

Risk communication can be only considered effective if it alerts the target audience as to what is hazardous, the extent of the danger and what should be done to protect oneself. Specific key messages that are based on accurate and timely information on counterfeit medicines will invoke action in the appropriate target audience.

In communicating the key messages, IMPACT needs to promote responsible media reporting by encouraging and assisting in information provision to ensure accurate and non-sensational coverage.

3.1.2 Terms of reference

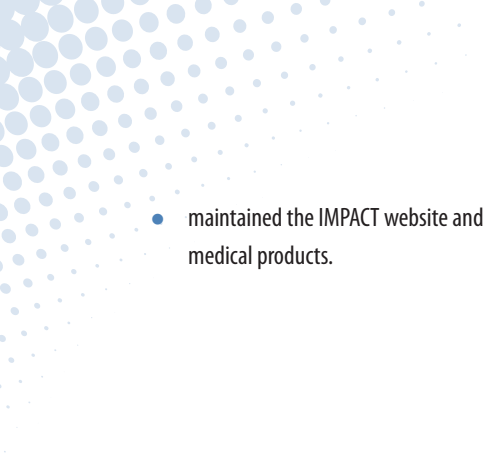
Currently chaired by Mr Ton Hoek, CEO and Secretary General of the International Pharmaceutical Federation.

The Working Group aims to:

- develop agreed messages and ensure IMPACT presence, as appropriate, at important national and international events;
- develop advocacy, risk communication and education strategies and materials taking into account the need to address specific target groups such as patients and health professionals;
- develop more effective collection and analysis of information on suspected and confirmed cases of counterfeit medical products and dissemination of confirmed cases as appropriate;
- develop initiatives to communicate risks of purchasing medicines from unknown sources (e.g. Internet);
- assist national authorities to develop risk communication and advocacy materials.

3.1.3 Main achievements so far

- developed and led the implementation of the IMPACT Communications Strategy. The communications strategy focuses on raising awareness of counterfeit medical products as a threat to public health worldwide in a safe and coordinated way that leads to action and providing a platform that reflects and communicates the objectives and actions of the IMPACT and all its working groups;
- collaborated with the World Health Professions Alliance (WHPA) in developing a toolkit for health professionals and patients to support activities to combat counterfeit medical products [see 3.3];
- collaborated with WHO and INTERPOL in developing media campaigns focussing on various key messages to different target audience.

- 
- maintained the IMPACT website and promote external print and electronic materials relating to counterfeit medical products.

3.2 WG COMMUNICATION: IMPACT COMMUNICATION STRATEGY

3.2.1 Introduction

Responding to the growing public health crisis of counterfeit drugs, in February 2006, the World Health Organization launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). At its core, IMPACT aims to build coordinated networks across and between countries in order to halt the production, trading and selling of fake medicines around the globe. IMPACT is a taskforce comprised of all the major anti-counterfeiting players, including: governments, international organisations, non-governmental organisations, enforcement agencies, pharmaceutical manufacturers and their associations, pharmaceutical wholesale associations as well as drug and regulatory authorities.

Counterfeit medicines and other health products can have harmful effects on patients' health, including death in worst case scenarios. These fake products are also detrimental to public health efforts to deal with diseases in countries which are already stretched thin with limited resources for health care.

The counterfeiting of medicines has been a problem for at least two decades in many countries around the world. As international markets expand and become globalized the problem has extended to all countries and regions; even though it remains more prevalent in developing countries. The increase in the commercial use of the Internet has also contributed to a growth of the problem as many fake products are sold illegally on unauthorized web sites.

3.2.2 Vision

The overall vision of IMPACT is to fight for eradication of all counterfeit medicines. All counterfeit medicines will be eradicated from supply chains of the developed world and be reduced by two thirds in the developing world by 2020. A communications campaign is now required create awareness of the risk, support program policy objectives and increase commitment from those who can influence change.

3.2.3 Target Groups

Distinct target audiences have been identified. Specific key messages will be tailored to each group for effective risk communications.

- Patients
- General Public
- Media
- Healthcare Professionals
- The Pharmaceutical Supply Chains
- Enforcement Officers
- Governments

3.2.4 The Communications Plan

Communications strategy should focus on two main objectives: increasing awareness of the risk and promoting policy remedies proposed by IMPACT.

It is recognized that a communications programme to address issues around the medicines supply chain cannot be seen in isolation and should be coordinated with the other IMPACT working groups. To this end, a separate policy objective communication strategy needs to be developed.

An internal communication protocol and structure has to be setup between the IMPACT Working Groups with a view to ensure consistent and regular information sharing. So as to effectively disseminate timely and accurate information about counterfeit medicines and means to combat them to the international audience, thus it is of utmost importance for the Communication WGs:

- to be apprised of the ongoing activities, accomplishment and output of the other WGs;
- to discuss accuracy and actuality of key messages with the relevant WG(s) and
- to provide feedback on communication campaigns and other activities to the other WGs.

The following strategies for risk communications are recommended:

3.2.5 Purpose

3.2.5.1 Why are we trying to communicate on counterfeit medicines?

The infiltration and sale of counterfeit medicines in the legitimate supply chain can cause death and misery to tens of thousands of patients around the world. Failure to act to prevent this criminal activity would be a fundamental breach of the trust placed in public health structures by patients. Any effective solution must drive immediate change, be effective in the long term and receive the support and active engagement and collaboration of all stakeholders managing the medicines supply chain.

Risk communication can be only considered effective if it alerts the target audience as to what is hazardous, the extent of the danger and what should be done to protect oneself. Specific key messages that are based on accurate and timely information on counterfeit medicines will invoke action in the appropriate target audience.

In communicating the key messages, IMPACT needs to promote responsible media reporting by encouraging and assisting in information provision to ensure accurate and non-sensational coverage.

3.2.5.2 What are our objectives?

As the IMPACT Communication Working Group:

- raise awareness of counterfeit medical products as a threat to public health worldwide in a safe and coordinated way that leads to action;
- educate on what is a counterfeit medicine and the appropriate and efficient reporting systems for suspected cases;
- provide a platform that reflects and communicates the objectives and actions of the IMPACT and all its working groups;
- provoke actions leading to policy change, utilising key messages that promote appropriate measures to combat counterfeit, as recommended by IMPACT. (in coordination with other working groups);

- promote behaviour change leading to the public and private procurement of medicines from known and reliable sources;
- increase the vigilance of healthcare professions and all stakeholders in the legitimate pharmaceutical supply chain for counterfeit medicines;
- utilise accurate and reliable information to support wider objectives such as the enforcement of pharmaceutical and penal legislation, efficient prosecution, application of Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP), increase national drug regulatory capacity and performance;
- promote exchange of information between regulatory, enforcement and private sectors, beyond boundaries. (in coordination with other working groups).

3.2.5.3 How will communication help meet these objectives?

Through media campaigns and news releases via a variety of communication channels in print, TV/radio, events and online information, IMPACT will reinforce the fact that all patients and the general public should only purchase their medicines from known and reliable sources.

Therefore, we aim to obtain commitment and action from key stakeholders who have the capability to prevent human misery resulting from infiltration of the genuine medicines supply chain at global, national and regional levels.

3.2.6 Key messages

3.2.6.1 What are the key messages?

Only get your medicines from known and reliable sources (Patients and General Public)

- patients and care-providers must make sure that they only buy from their legal outlets, such as pharmacies and appropriate trained personnel such as pharmacists
- the general public must be educated about what is a counterfeit medicine. According to the WHO definition, a counterfeit medicine is 'a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.'

Counterfeit medicines are a threat to personal and public health worldwide (Media)

- counterfeit medicines, including the entire range of activities from manufacturing to providing them to patients, is a vile and serious criminal offense that puts human lives at risk and undermines the credibility of health systems

When treatment fails, consider counterfeits as possible suspects (Health Professionals)

- health professionals need to consider counterfeit medicines as a reason for non-response or unexpected response in pharmacotherapy in the patients they care for.

The road to success-the joint combat against counterfeits of all stakeholders in the supply chain (Pharmaceutical Supply Chains)

- in order to successfully combat counterfeits a coordinated effort of all public and private stakeholders in the pharmaceutical supply chain is required where
 - all share accountability;
 - all bear responsibility;
 - all invest resources.
- there is need for a multi-layered strategic approach to harmonized regulations and investigative efforts;
- there is a need for securely tightened supply chains whose individual components commit to doing business with trusted partners only. .

Medicines should not be traded as a commodity (Pharmaceutical Supply Chains and Governments)

- one should be aware of the specific nature of medicines since their purpose is to cure patients from diseases-counterfeit medicines endanger patients' safety. Therefore the handling of medicines - no matter where in the supply chain-demands specialised and knowledge-based attention.
- the legitimate pharmaceutical supply chain as the secure channel to distribute medicines to patients around the world needs to be strengthened in order to be maintained in the long run.
- all stakeholders in pharmaceutical supply chain should endeavour to protect the integrity of the supply chain; also a stronger role for pharmacists at every step of the supply chain could reduce the risks of medicine counterfeiting.

When existing laws are not adequate and rigorously enforced, crimes such as counterfeiting tend to perpetrate. (Enforcement officers and Governments)

- governments must intensify their attention to the existence and dangers of counterfeit medicines.
- cooperation, collaboration and sharing of information beyond boundaries between Law Enforcement Agencies is a necessity for effective investigation and prosecution.
- there is a need to raise the awareness of IMPACT among international organizations and national legislative, regulatory and enforcement authorities in order to strengthen international action against counterfeit medicines

Communications

3.2.6.2 How will we communicate our key messages?

- a major goal is to increase media activities on the international level, and where effective, at key national events. We want to provoke action within all target groups to encourage them to be agents of policy change.
- there is a need for an international ambassador/spokesperson for IMPACT, especially in expanding the TV/radio/newspaper/representation/media events of IMPACT.
- millions of healthcare professionals and their national associations can be reached through the Member networks of WMA, FIP, ICN, IFPW, GIRP and FDI by sending out press releases and position statements for advocacy.

- toolkits for healthcare professionals, patients and the general public can be distributed at local pharmacy, clinics and hospitals.
- industry consensus can be created amongst manufacturers and wholesalers on the level of individual responsibility required to prevent supply chain infiltration.
- promote protection of supply chain integrity as a public health priority for health policy makers can be emphasized by highlighting the scale of the problem and its impact on patients.
- stakeholders at all levels can be equipped with the awareness and education required to avoid buying medicines from illicit or dubious sources and, to alert appropriate authorities in case of suspicious medicine, and for patients, their healthcare providers. Counterfeit reporting should be widely promoted to increase rate of reporting.

3.2.7 Activities

3.2.7.1 What specific tools, tactics, techniques, events or publications will we use?

- generate an IMPACT consensus statement and publish as a firm international commitment to action;
- create a simple campaign theme to drive and promote communications activities;
- identify a high-profile, influential international anti-counterfeiting ambassador to champion the IMPACT agenda;
- WHPA and IAPO both have organisational aims (and some resources) to develop toolkits of relevance in 2007/2008;
- WHPA will be developing a counterfeit medicines toolkit for healthcare professionals;
- WHPA is also considering the development of a counterfeit medicines toolkit for patients' organizations;
- IAPO will commence development of a Patient Safety Toolkit for patients' organizations in mid 2007 which will have a section on counterfeit medicines;
- surveys of the patients would provide valuable data on the current awareness, and behaviour regarding medicines and counterfeit medicines, which would help in the development of appropriate communications materials. In addition it would be used as a benchmark and could be repeated periodically (e.g. in 3 or 5 years) to see any changes in awareness or behaviour as a result of IMPACT;
- IMPACT presence at national events for advocacy and dissemination of key messages
- create momentum and put on the agenda at key international industry meetings (packaging, wholesaling, medical and pharmacy);
- to organise a briefing at the May 2007 World Health Assembly, Geneva, Switzerland;
- Commission a BBC/CNN World TV documentary on the impact of counterfeit medicines;
- use the Internet to create broad international communication of key messages to policy makers, healthcare professionals and patients;
- create a database of key journalists - with intelligence on where they get information, how they use it and how we can input into that process etc. Both international and national level journalists;

- organise a Media Workshop - in 2007 hold a workshop with journalists to inform them about IMPACT and build links and working relationships (consider if appropriate to hold in London or Geneva to link in with organisations and media in these areas.

3.2.7.2 What are the best ways of getting feedback from our audience?

- feedback forms at all media events and IMPACT related conferences;
- through feedback by surveys of healthcare professionals, patients and general public;
- local stakeholders meeting to discuss supply chain action plan;
- monitor government decisions on tightening regulations or increases customs activity with regards to counterfeit medicines control;
- “Design a poster on the dangers of counterfeiting” campaign for students and professional artists, sponsored by the industry (manufacturers and wholesalers).

3.2.8 Resources

3.2.8.1 What are the critical pieces of information that we need?

From each working group we would need similar information as outlined in this document, i.e.

- What is the progress of the respective working group?
- What are the identified key messages - to whom and when should they be communicated?
- How can the communication Working Group support your Working Group?
- What are the current activities?
- What is the associated timeline?

3.2.9 Evaluation

3.2.9.1 How will we know if we have reached our objective?

Increased publicity and media coverage by journalist in newspaper, TV, radio and journal magazines

The survey could be repeated periodically (e.g. in 3 or 5 years) to see any changes in awareness or behaviour as a result of IMPACT. We can also repeat the focus group discussions

3.2.9.2 How will we track our progress?

To monitor IMPACT's representation in a calendar of events



	Patients	General public	Media	Healthcare professionals
Main key message	only get your medicines from know and reliable sources	only get your medicines from know and reliable sources	counterfeit medicines are a threat to personal and public health world-wide	when treatment fails, consider counterfeits as possible suspects
Key points	patients and care-providers must make sure that they only buy from their legal outlets, such as pharmacies and appropriate trained personnel such as pharmacists and they should be educated about what is a counterfeit medicines	general public must make sure that they only buy from their legal outlets, such as pharmacies and appropriate trained personnel such as pharmacists and they should be educated about what is a counterfeit medicine	counterfeit medicines including the entire range of activities from manufacturing to providing them to patients, is a vile and serious criminal offense that puts human lives at risk and undermines the credibility of health systems	health professionals need to consider counterfeit medicines as a reason for non response or unexpected response in pharmacotherapy in the patients they care for
Past activities (2007 to may 2008)	IAPO is developing a patient safety toolkit for patients organizations which will have a section on counterfeit medicines			WHPA has developed a counterfeit medicines toolkit for health care professionals. A wider distribution plan for this toolkit needs to be in place. Available in En. and on www.whpa.org
Current activities for the future (june 2008 to dec 2009)	a patient guideline on buying medical products and services over the Internet will be developed	the concept "World Anti-Counterfeiting Day". "safe medicines day should be further explored with the planning group. Opportunities for a public service announcement on combating counterfeit medical products project will be explored	an IMPACT press release needs to raise the awareness of IMPACT among international organizations and nationale legislative, regulatory and enforcement authorities in order to strengthen international action against counterfeit medicines	further translation of the WHPA toolkit can be done. Requests for the french version has already been received from organisations working in Africa

	Pharmaceutical supply chains	Enforcement officers	Governments
Main key message	the road to success-the joint combat against counterfeits of all stakeholders in the supply chain	when existing laws are not adequate and rigorously enforced, crimes such as counterfeiting tend to perpetrate	medicines should not be traded as a commodity and when existing laws are not adequate and rigorously enforced, crimes such as counterfeiting tend to perpetrate
Key points	in order to successfully combat counterfeits a coordinated effort of all public and private stakeholders in the pharmaceutical supply chain is required where all share accountability; all bear responsibility; all invest resources	cooperation, collaboration and sharing of information beyond boundaries between law enforcement agencies is a necessity for effective investigation and prosecution	there is a need to raise the awareness of IMPACT among international organizations and national legislative regulatory and enforcement authorities in order to strengthen international action against counterfeit medicines
Past activities (2007 to may 2008)	an IMPACT global forum was organised in Singapore, bringing together technology developers of anticounterfeiting technologies and key impact stakeholders	developing two short films one in Mli and one in Venezuela. Both films (3 minutes each) describes (in different contexts) an enforcement officer who loses a member of his family because of a counterfeit medicine	FIP organised a briefing at the 61 st WHA May 2008, for IMPACT on the topic of the role of governments, NGOs and other international organizations in combating counterfeit medicines
Current activities for the future (june 2008 to dec 2009)	a position statement on Internet pharmacy can be made, based on the IMPACT guidelines on trade of medical products and services over the Internet	a documentary series of short videos on the IMPACT of counterfeit medicines on public health will be develop in collaboration with Interpol with a focus on illustrating the dangers of the illicit supply chain, adapted to at least 2 regions of the world (Africa and South America)	5 IMPACT factsheets will be develop. highlighting 10 key messages relating to the 5 working areas of IMPACT and its stakeholders

3.3

BE AWARE TOOLKIT

Document endorsed by the IMPACT at its second General Meeting in Lisbon, 2007.

Preamble

IMPACT requested the World Health Professions Alliance (WHPA) to develop a toolkit for health professionals and patients, to assist dentists, nurses, pharmacists and physicians to tackle counterfeit medicines in their daily practice. The kit includes an overview of the situation and suggestions as to what health professionals can do to help fight counterfeit medicines, and some practical tools (e.g. reporting forms, posters) that can be downloaded from the IMPACT website (<http://www.who.int/impact/news/beaware/en/index/.html>). We encourage health professionals to use any or all documents as they judge appropriate and to share these with colleagues in the effort to raise awareness.

Dear Colleagues

Counterfeit medical products are unsafe and ineffective. They result in wasted resources spent on purchasing, inventory, transport and dispensing with little or no effect, or even cause harm to the patient. Counterfeit medicinal products threaten patient safety by, at best, causing no improvement or, worse, causing added burden of disease and even death. They endanger public health by increasing the risk of antimicrobial resistance, and they undermine patients' trust in health professionals and health systems, who are seen not to be able to provide an adequate treatment. Public health and patient safety are being put at risk and now is the time for you as a health professional to act.

The World Health Professions Alliance WHPA represents more than 26 million health care professionals in more than 130 countries. WHPA is an alliance of the International Council of Nurses (ICN), the International Pharmaceutical Federation (FIP), the World Confederation for Physical Therapy (WCPT), the World Dental Federation (FDI) and the World Medical Association (WMA). WHPA is extremely concerned about the infiltration and sale of counterfeit medical products of the legitimate supply chain in causing life threatening, adverse effects in patients.


Working together as health professionals, we have a responsibility to ensure that our patients receive safe and appropriate medications. With this WHPA "Be Aware, Take Action" toolkit we provide dentists, nurses, pharmacists, physicians and physiotherapists with tools and strategies to advocate for appropriate investments in the education and capacity building of health professionals to detect counterfeits and to safely inform colleagues and patients.

We want to raise the 'suspect' index for counterfeit medical products where patients on treatment do not report getting better or appear with new unexpected symptoms. At the same time WHPA is keen to manage the risk communication aspect of this effort, ensuring patient adherence to medical products. We encourage health professionals to use any or all documents as they judge appropriate and to share these with colleagues in the effort to raise awareness.

Thank you for joining the World Health Professions Alliance in the fight against counterfeit medical products. Public health and patient safety are being put at risk and now is the time to act.

WHPA is happy to share this resource with the WHO International Medical Products Anti-Counterfeiting Taskforce (IMPACT) for its use and further dissemination.

Sincerely,
International Council of Nurses
International Pharmaceutical Federation
World Confederation for Physical Therapy
World Dental Federation
World Medical Association



3.3.1 The Be Aware, Take Action toolkit

This toolkit has been designed to help educate and improve the capacity of health professionals to detect, report and prevent counterfeit medical products. Three target audiences are catered for – health professionals, patients and public health advocates.

This toolkit contains:

- general information Fact Sheets for health professionals, patients and public health advocates on counterfeit medical products;
- campaign postcards;
- sample Reporting Form for health professionals;
- be Aware, Take Action poster;
- a medicines Checklist poster for waiting rooms and pharmacies;
- the WHPA Joint Statement of Counterfeiting of Medical Products;
- frequently Asked Questions (FAQ) sheet.

3.3.2 How to use these materials?

At the clinic or hospital:

Display the Be Aware, Take Action poster prominently around the clinic and in the doctor's room. Make sure that patients can easily see the Medicines Checklist poster in their waiting areas and before they leave with their medicines. Make fact sheets and postcards available for patients to take.

At the pharmacy:

Display the Be Aware, Take Action poster prominently at the pharmacy. Make sure that patients and customers can easily see the Medicines Checklist poster at the dispensing points and before they leave with their medicines. Make fact sheets and postcards available for patients to take.

For health professionals and public health advocates:

Familiarize yourself with the sample reporting form (especially if there are no standard forms in your country). If you need basic information about counterfeit medical products, read the FAQ and WHPA joint statement. Always check with respective health professional associations and drug regulatory authorities for the latest up to date information about incidences of counterfeit medical products in your country.

Additional copies of the Be Aware, Take Action toolkit can be ordered from the World Health Professions Alliance email whpa@wma.net. PDFs can be downloaded from www.whpa.org/counterfeit_campaign.htm.

Material from this toolkit may be reproduced for educational purposes, provided WHPA Be Aware, Take Action Toolkit is acknowledged as the source, and that the message isn't changed.

This toolkit has been developed for use by IMPACT and has been translated into French and Spanish as of October 2010. Work is ongoing to extend the toolkit to more languages and countries.

3.3.3 FACT SHEET [health professionals]

3.3.3.1 Communication with patients

Many counterfeit medical products are first detected by patients. Health professionals should share any concerns about counterfeit medical products with their patients in a safe and non-threatening manner, being careful not to unnecessarily undermine adherence to treatment.

A patient information leaflet can be available in waiting rooms, on counters, and in common areas. A poster can be placed on the walls of medical and nursing practices, pharmacies, clinics, hospitals and community centres. Patients may then ask about the subject or wish to discuss it spontaneously.

There are several points of contact where the subject of counterfeit medical products can be discussed, for example at consultation, during diagnostic tests, when the treatment is being prescribed, at the medical product purchase point, and when monitoring treatment. A patient may feel vulnerable because of being unwell; discussion might be experienced as threatening or invasive.

3.3.3.2 It is important to query gently...

Where patients bought or will buy the medical product. Emphasis can be placed on the importance of buying medical product from a pharmacy or other known and reliable sources.

For example: "Did you purchase the medical product from a known and reliable source?"

What patients should look out for when they buy medical products. It can be suggested that patients check the packaging, the product and the patient leaflet when they purchase medical product.

For example: "Was the packaging of the product intact, properly sealed, clearly labelled with dosing, manufacturer, batch number, and expiry date?"

How the medical product is expected to take effect. By explaining what should happen when patients take medical products, health professionals can help patients identify anything unusual.

For example: "Did the medical product cause any unexpected side effects?"

When If a medical product is supposed to start relieving symptoms within 24 hours for example, then patients should know, so that if the medical product does not take effect, they can notify their health professional.

For example: "Has the medical product taken longer than anticipated to have an effect?"

3.3.3.3 In daily practice

When prescribing, dispensing or administering medical products, health professionals should explain to patients in what way the medical product should improve their health and what benefits and/or side effects patients may experience. It can be suggested that medical products should only be obtained from known and reliable sources.

3.3.3.4 Health professionals can encourage patients to:

- buy their medical products from known and reliable sources.
- purchase their medical products from properly trained personnel, such as properly qualified pharmacists.
- tell their health professional about any problem, lack of reaction, overreaction or adverse event after using the medical product.
- discuss the possibility that a medical product may be counterfeit where there is no response or an unexpected response to the medical product.
- remain vigilant about the possibility of counterfeit and substandard medical products if they buy from the internet.

3.3.3.5 If counterfeit medical products are suspected, health professionals should:

- ask patients to bring in their medical product. Compare the medical product with other samples.
- act quickly to change the medical product if it is substandard or counterfeit, so the patient is not left without treatment.
- report the suspected counterfeit to the appropriate authorities. Report first to your manager if you work in a health facility. Depending on the national procedures you may also want to report to the ministry of health, your national health professional association, police, and customs authorities.
- reassure the patient on the way forward and reassess therapy accordingly.

3.3.3.6 Taking precautionary measures

It is important that once a counterfeit medical product has been identified, precautions are taken to prevent others from being exposed.

- warn colleagues and management that counterfeit medical products have been identified in the workplace;
- suggest that health professionals be vigilant in case more counterfeits are circulating;
- warn the relevant drug regulatory authorities that counterfeit medical products have been found;
- spread the word that the criminals are being sought: this sometimes dissuades further action;
- verify whether any patients have not responded to or had an unexpected response to medical products;
- reassess possibilities that other counterfeit medical products may be present;
- follow up with patients if counterfeiting has been confirmed, to discuss next steps in treatment;
- address any questions and concerns patients may have through information and discussion.

3.3.3.7 What can health professionals do?

There are some key steps that health professionals can take to identify and report counterfeit medical products, to help fight such criminal practices and make treatments safer.

BE AWARE

Be observant if anything about a medical product is unusual or different, consider counterfeit medical products.

Evaluate if treatment fails, or has an unexpected effect, consider counterfeit medical products as possible suspects.

Acquire as much information as possible about the product, its packaging, pharmaceutical properties and usage.

Where find out whether product was purchased from a known and reliable source.

Actively inform your health professional colleagues and other patients if medical products have been confirmed as counterfeit.

Remove any suspect medical products. Report the suspected counterfeit to the relevant health authorities.

Educate your colleagues, patients and the public to identify and avoid

3.3.4 The Internet and counterfeit medical products¹

There is a growing trend with more and more people buying medical products online. In over 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit.

Health professionals communicate the risks and dangers of buying medical products on the Internet

This is a role that health professionals can play in their daily interactions with patients. It is important to identify the needs and concerns of patients in paying for their medicines and in obtaining a regular supply of affordable and quality medicine in their communities. Sufficient patient counselling about the proper channels when buying medicines should always be done to avoid misconceptions of the risks of buying medicines from the Internet.

Understand the patient's motivation

Every patient might have a reason to be tempted to go online to buy their medicines. It could be related to:

- **Reducing out of pocket payments.** This is particularly true in countries where social insurance coverage is weak or insufficient and where medicines prices are relatively higher. For those patients who have to pay, most if not all medicines out of their pocket, buying from the Internet could be seen as a way of reducing their treatment costs.

- **accessing drugs without prescription:**³ It is often the availability of a prescription only medicine without a prescription not the price of the product which is important to the patient. This may perpetuate incidents of drug abuse or misuse.
- **being anonymous:** The physiological unwillingness to discuss “embarrassing” lifestyle issues, such as erectile dysfunction and depression. However, little is also known about confidentiality of patient information when using illegal Internet drug outlets.
- **increasing the range of possible treatments:** Access to products or medicines that are not yet authorized in their country.
- **increasing access to medicines:** The geographical limitation to the patient’s access to a brick and mortar pharmacy. This is especially evident in rural areas where the density of pharmacy serving the community is rather low, and consequently if the pharmacy is far from the house of patients.

Explain and give examples of potential dangers to patients

The message needs to be, “Do not take the risk of buying your medicines from unknown sources, such as the Internet. If you must buy from the Internet, ensure that the website is that of a pharmacy you know and trust.”

The advent of much more educated and more informed consumers are challenging the health professionals in providing accurate information and acceptable prices for the medicines that they need, even though in some cases, these consumers may be obtaining their information from unreliable sources. Health professionals are in a position to educate patients on the reliable sources of online medical information.

Provide patients with tools and information

If patients insist on buying their medicines from the Internet, health professionals can educate them to check for the following information from the e-pharmacy website:

- name of the pharmacy providing the service.
- the geographic addresses at which the pharmacy is established and its details (telephone and fax numbers) including e-mail address which allow it to be contacted rapidly and communicated with in a direct and effective manner.
- professional title of the pharmacist responsible and country where it has been granted.
- professional body with which the pharmacist responsible is registered and the relevant supervisory authority (where applicable).
- reference to the applicable professional rules in the country of establishment and the means to access them (a link to, or the geographic address of the body in their possession).

1. This material has been adapted from Xuanhao Chan, L. B. (2008). Safe internet buying of medicines: why and how pharmacists should help. *European Journal of Hospital Pharmacy*, 14 (3), 61-63

3.3.5 FACT SHEET [advocates]

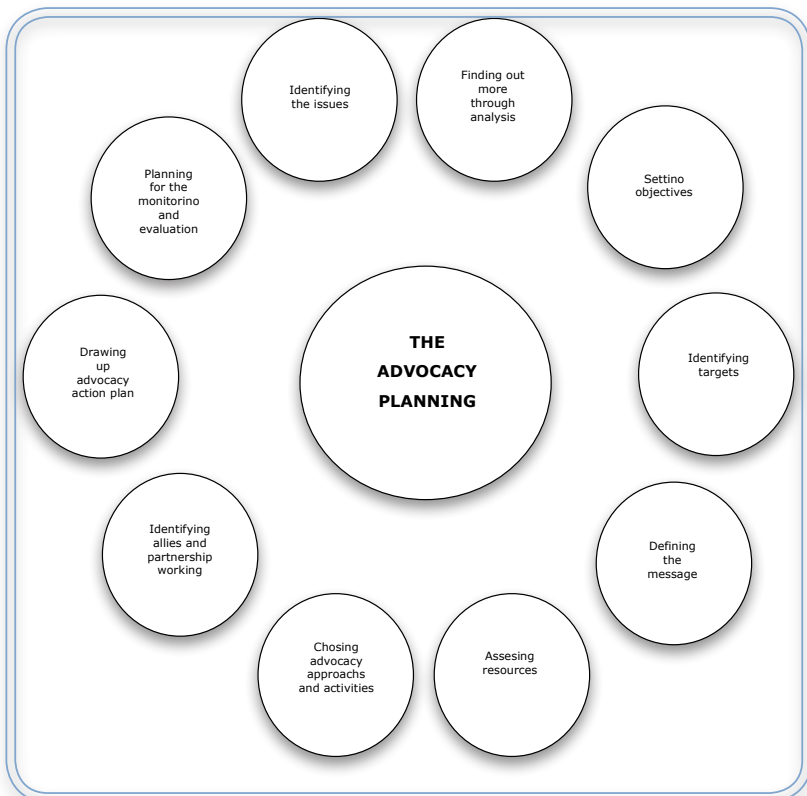
3.3.5.1 Effective advocacy for change

As a public health advocate, you know the importance of being vigilant when it comes to counterfeit medical products. Actions that you can take in your workplace, within your professional organization or towards health policy makers or the public, can help ensure patient safety. There is no 'one size fits all solution' because each country has a unique situation in relation to counterfeit medical products, regulation and enforcement, public awareness and the healthcare system. There are however some basic principles which you can adopt.

3.3.5.2 Useful tips

- advocacy is a long-term process so once you have introduced your idea, you may need to look for further opportunities to communicate with key stakeholders;
- change doesn't happen quickly so you may need to repeat your message many times;
- offer positive solutions to the counterfeit medical products issues that you face;
- identify partners and take time to build strong relationships.

3.3.5.3 Advocacy planning cycle



Identify what you want to change.

Defining the problem will be different for each country. It could be lack of coordination on counterfeit medical products amongst health professionals, or a boom in the public buying medicines from unknown sources via the Internet.

Analyze the issue and identify the solution

This step involves gathering key facts and background information, identifying who you can work with, the target audience and setting specific objectives.

Some questions could be:

- What do we know about counterfeit medical products in our country and what information can we use?
- What do we specifically want to change? (Try to make SMART objectives – Specific, Measurable, Achievable, Relevant and Time-critical).
- Who do we want to influence?
- Who could we partner with to achieve our objectives?
- How does the system work? What is the best way to work for maximum results?

This can help lead to a tailor-made solution. For example, development of closer cooperation between the health professions so a unified group can advocate to healthcare decision makers for increased resources to fight counterfeits. Or it might be a campaign to increase awareness of the risks of buying medical products over the Internet.

Identify success indicators for each objective, to include inputs (time, resources), outputs (reports, visits, events), outcomes (media coverage, changes in policy, increased budget allocations) and impact (the effect of policy change on daily lives).

Choosing your approach and activities

The issue you have identified, the resources you have available, and who you want to reach will influence the approach you take.

- You may want to involve co-workers to raise awareness locally to issues of counterfeit medical products or you may want to encourage your health professional organization to take a more active stance on the issue.
- You may decide to use the media to get your message across. In this case, your health professional association may be able to help. Healthcare decision makers are aware of what is being said in the media on health issues and this might help you to have more influence.
- It could be possible to hold a briefing for politicians in a healthcare environment or in a parliamentary setting.

Select the appropriate tools and tactics

This toolkit contains Frequently Asked Questions about counterfeit medical products, to which you can add country-specific information. There are also fact sheets for health professionals, advocates and patients; campaign postcards; posters for waiting rooms and staff rooms; and the WHPA Joint Statement on Counterfeiting of Medical Products. A power point presentation can be downloaded from the WHPA counterfeit campaign website: http://www.whpa.org/counterfeit_campaign.htm

SAMPLE ADVOCACY PLAN

Objective	Target audience	Key messages	Activity	Indicator
Have health professionals develop and commit to a local action plan against counterfeits	Health professionals, professional association	Counterfeit medicines are a threat to patient safety and public health, and health professionals are taking action	Build a health professionals network involving at least five different professions to demand change on counterfeit medical products	Network of health professionals representing five different professions is formed and adopts action plan
Communicate about the risks of buying medical products over the Internet to at least 20% of 25-55 year old	Patients and public	Only buy your medical products from know and reliable sources	Public awareness campaign with postcards, social media such as Facebook, media releases and interview, letter to the editor	Number of visits to related information website, reported contacts with health professionals
Key politicians commit to putting control of counterfeit medical products on the health policy agenda	Members of parliament	Counterfeit medical products will only be eradicated framework of effective coordination, cooperation and action at the global level to assure necessary quality and safety of medicines in international and national supply chain	Health professionals briefing at parliament building, with anti-counterfeit posters, position paper, key spokespeople from national health professionals associations	MP champions for the anti-counterfeiting public health cause identified and they raise the issue of public health and counterfeits in health care policy and plan

Measure the impact of your efforts

It is important to measure the results of your efforts, based on the success factors that were set for each objective.

3.3.6 FACT SHEET [patients]

You can help keep medical products safe

If you are buying or using medical products, please be aware that there are counterfeit medical products that may threaten your health and that of your loved ones.

Reduce your chances of taking a counterfeit medical product by buying your medical products only from known and reliable sources.

BE AWARE

Be observant if there is anything unusual about a medical product and packaging, tell your health care professional

Evaluate if your medical product has an unexpected effect or no effect, consider counterfeits as a possible reason

Acknowledge tell your health professional what effect th medical product had on you

Where tell your health professional where the medical product was bought, particulary if it was from a market, over the Internet, or in the street

Actively inform your health professional and other patients who might have received the medical product, about your experience

Report the suspected counterfei to your health professional

Educate your friends and family about the risk of counterfeit medical products

What is a counterfeit medical product?

A counterfeit medicine is a copy of a real medicine or medical device, which may have mislabelling with regards to its name, or it might look just like an authentic medical product. Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient quantities of active ingredients or with fake packaging.

What can patients do to fight counterfeit medical products?

Patients need to be aware that counterfeit medical products exist and be encouraged to purchase medical products from safe sources, such as registered pharmacies. In addition, patients should suspect any unnaturally low-priced medical product and be attentive to packaging and presentation of medical products. Any unexpected reactions to the medical product should be communicated to your health professional.

What about buying medical products from online pharmacies?

Know that in more than 50% of cases, medicines purchased over the Internet, from illegal sites that hide their address, have been found to be counterfeit. If you buy from the Internet, first ensure that the website is that of a pharmacy you know and trust. A reputable online pharmacy should provide the following information:

- name of the pharmacy providing the service;
- the geographic addresses at which the pharmacy is established and its details (e-mail address, telephone, and fax numbers);
- professional title of the pharmacist responsible and where title was granted;
- professional body with which the responsible pharmacist is registered and the relevant supervisory authority;
- reference to the applicable professional rules in the country of establishment and how to access them.

Counterfeit medical product sample reporting form (for health professionals)

If you suspect you have discovered a counterfeit medical product, you should report this immediately to the appropriate authorities in your country. Report first to your manager if you work in a health facility. Depending on the national procedures you may also want to report to the ministry of health, your national health professional association, police and customs authorities, etc.

- submit a report to the relevant drug regulatory authority;
- keep samples of the suspected medicine or medical product (including packaging, package insert etc.);
- check current stock;
- cease dispensing and secure suspect counterfeit medical products until results from further analysis can be obtained;

Product details

Product name

Supplier Name (from label)

Manufacturer

Product licence Number (from label)

Dosage form E.g. tablet, capsule, cream etc

Strength (from label)

Container type / size

Batch / Lot number

Expiry date (from label)

Is sample available for lab testing? YES / NO

Please give details of the reported defect and details of any associated clinical incident

This report is made by:

Name:

Contact number:

Email address:

POSTER FOR PHARMACIES

Before you go, have you checked?

- Is the container and closure properly sealed to protect the drug from the outside environment?

- Is the strength - the amount of active ingredient per unit - clearly stated on the label?

- Is the dosage clearly indicated?

- Is the manufacture date clearly indicated on the label?

- Is the expiry date clearly indicated on the label?

- Are the tablets uniform in shape, free of powder, non-sticking and not broken, cracked, split or with pinholes?



Often we cannot determine a counterfeit medical product visually because the packaging quality and finishing of some counterfeits makes detection very difficult.

Ask your health professional if you are unsure about your medicines.



World Confederation
for Physical Therapy



WHPA JOINT STATEMENT ON COUNTERFEITING OF MEDICAL PRODUCTS

Background

All health care professionals have a common goal to protect the well-being of patients in all parts of the world from poor quality, substandard and counterfeit medical products. Pro-active steps must be taken in collaboration with Governments and other key stakeholders of the legitimate supply chain such as the pharmaceutical manufacturers and distributors to ensure the quality, safety and efficacy of all medical products available in countries, in accordance with recognised international standards. This form of quality assurance applies to both branded and generic products, to both the private and public sectors, and to both imported and locally manufactured products.

The World Health Professions Alliance WHPA represents more than 26 million health care professionals in more than 130 countries and is an alliance of the International Council of Nurses (ICN), the International Pharmaceutical Federation (FIP), the World Confederation for Physical Therapy (WCPT), the World Dental Federation (FDI) and the World Medical Association (WMA). WHPA is extremely concerned about the infiltration and sale of counterfeit medical products of the legitimate supply chain in causing life threatening adverse effects in patients.

Counterfeit medical products must be considered to be unsafe and ineffective. They result in wasted resources spent on purchasing, inventory, transport and dispensing with little or no effect or even cause harm to the patient. Counterfeit medicinal products threaten patient safety by, at best, causing no improvement or, worse, causing added burden of disease and even death; endanger public health by increasing the risk of antimicrobial resistance; and patients' trust in health professionals and health systems, who are seen not to be able to provide an adequate treatment. Public health and patient safety are being put at risk and now is the time to act.

Health professions are crucial to combating counterfeit medical products. By visual inspections, nurses, pharmacists, physicians, dentists and physical therapists who are constantly in contact with medicines and medical devices may be able to detect anomalies in the physical appearances of medical products and trigger investigation. Health professionals need to increasingly consider counterfeit medicines as a reason for non-response or unexpected response in pharmacotherapy in the patients they care for. Yet, for health professionals to be able to effectively play their role, it is necessary that national authorities set up effective systems for the collection of information indicating possible counterfeits signal, verify and investigate this information and feed back the results to those who have provided the information.

This global and deadly phenomenon of counterfeit medical products will only be eradicated through an agreed framework of effective coordination, cooperation and action at the global level. The WHPA agrees to step up its commitment and promote the awareness of the dangers posed by counterfeit medical products among health professionals, consumers and patients and their national governments.

The Seven key principles

Against this background, the WHPA identifies the following 7 key principles for enabling international cooperation and exchange of information among relevant stakeholders involved in detecting and combating counterfeit medical products:

1. The primary focus of combating counterfeit medical products is the protection of public health and recognition that the main victims of counterfeiting are patients.
2. Counterfeiting of medical products, including the entire range of activities from manufacturing to knowingly providing them to patients, is a vile and serious criminal offense that puts human lives at risk and undermines the credibility of health systems.
3. A comprehensive strategy to combat counterfeiting of medical products require an active participation that involves all stakeholders of the public sector and the civil society through organizations representing health professionals, patients, manufacturers, distributors, and as well as the media and governments.
4. Education of health professionals is crucial for detection and prevention of counterfeit medical products and is required in order for them to educate patients and populations about the risks of buying counterfeit medical products from unknown and unreliable sources.
5. Increased vigilance by health care professionals and patients can help make public and individual health safer. When prescribing, dispensing or administering medicines, health professionals need to consider and report counterfeit medicines as a reason for non-response or unexpected response in pharmacotherapy in the patients they care for.
6. International specialised agencies responsible for procuring and distributing medical products should identify substandard and counterfeit medical products and publish a list of these products, so that steps can be taken to remove these medical products from the market when discovered.
7. National governments are positioned to play a key role in eliminating counterfeit medical products by the enforcement of pharmaceutical and penal legislation through efficient prosecution, by ensuring adherence to Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and Good Pharmacy Practices (GPP) and by increasing national drug regulatory capacity and performance.

A.J.M. Hoek
General Secretary &
CEO, International
Pharmaceutical
Federation (FIP)

Otmar Kloiber
Secretary General,
World Medical
Association

David Benton
Chief Executive Officer,
International Council of
Nurses

David C. Alexander
Executive Director, FDI
World Dental Federation

Brenda J. Myers
Secretary General,
World
Confederation for
Physical Therapy
(WCPT)

March 2010

3.4 THE IMPACT VIDEOS

Presented by the Communication Working Group at the third General Meeting of IMPACT, Hammamet 2008 |ADN Production| [see CD]

3.4.1 Message of the first video



The mission of IMPACT is to promote and strengthen international collaboration to fight counterfeit medical products.

Every day in some countries, the production of counterfeit drugs is a common reality.

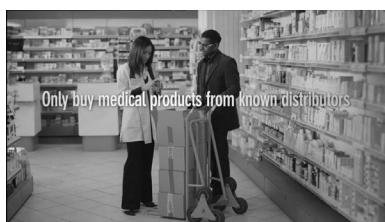
Every day patients die from counterfeit medical products bought on illegal and legal markets.

Every day IMPACT mobilizes global awareness and action against counterfeit medical products building capacity, sharing expertise, seeking solutions. IMPACT takes actions. IMPACT! All together, winning the race, saving lives. In February 2006 WHO created the first global initiative, known as the International Medical Products Anti-Counterfeiting Taskforce: IMPACT.(...)

www.who.int/impact

[IMPACT, International Medical Products Anti-Counterfeiting Taskforce]

3.4.2 Message of the second video



Every year millions of patients are exposed to counterfeit medical products.

Health professionals: be aware. Be responsible.

IMPACT supports you as a health professional.

Only buy products from known manufacturers.

Quality and safety are the most important factors when buying medical products. IMPACT is on your side to help you make the right choice. Only buy products from known distributors.

Ensure that what you buy is what you receive. IMPACT needs you to be aware. When treatment fails consider counterfeit medical products as a reason. Always ask your patient where they buy medicines. Tell them of the dangers of counterfeit medical products. Counterfeit medical products kill patients. Be aware.

IMPACT. All together, winning the race, saving lives. Find out how health professionals can combat counterfeit medical products. www.whpa.org [World Health Professions Alliance].

3.5 IMPACT WEBSITE

3.5.1 Introduction

The IMPACT communication Working Group has been instrumental in updating the IMPACT web pages in coordination with the IMPACT Expert Working Groups and the IMPACT Secretariat. The following information are available on www.who.int/impact.

In addition, you may also find news, useful links and relevant background materials of IMPACT meetings.

3.5.2 Home page

Counterfeit medical products are a major public health risk for all communities. The phenomenon has grown in recent years due to counterfeiting methods becoming more sophisticated and to the increasing amount of merchandise crossing borders.

WHO has responded to the challenge by creating a global coalition of stakeholders called IMPACT (International Medical Products Anti-Counterfeiting Taskforce). The taskforce, created in 2006, has been active in forging international collaboration to seek global solutions to this global challenge and in raising awareness of the dangers of counterfeit medical products.



3.5.3 About us

Responding to the growing public health crisis of counterfeit drugs, in February 2006, the World Health Organization launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). At its core, IMPACT aims to build coordinated networks across and between countries in order to halt the production, trading and selling of fake medicines around the globe. IMPACT is a taskforce comprised of all the major anti-counterfeiting players, including: governments, international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturers associations and drug and regulatory authorities.

You may download the Terms of Reference and FAQ on this website.

3.5.4 IMPACT working groups

As per its Terms of Reference, IMPACT may establish Working Groups to address and advise IMPACT Participants on specific issues relating to its goal and objectives, including the coordination of country focused initiatives. Working Groups will be led by a Chairperson, selected by the General Meeting. The Chairperson must be a Participant. For the beginning, 5 Working Groups have been established as outlined below.

Working Groups must ensure that Participants and Invited experts have the appropriate expertise. As long as this is ensured, Working Groups' composition will aim at ensuring representation of the different stakeholders. The Planning Group and the Secretariat will have to ensure that these principles are met.

Each Working Group will develop proposed work plans, report and submit proposals to the General Meeting through the Planning Group.



4

**WORKING GROUP
ON ENFORCEMENT**

4.1 OVERVIEW OF THE IMPACT WORKING GROUP ON ENFORCEMENT

4.1.1 Preamble

Today, nothing short of a global approach to inhibiting the flow of potentially deadly counterfeit medical products is required. Every country around the world suffers the same problems. The global trade in medicines and medical devices necessitates that countries actively work together and commit to reducing the international trade in counterfeit medical products. Organised criminals trading in counterfeit medical products have well developed worldwide networks which do not recognise any borders between countries. Working with well informed law enforcement officers at a global level makes a difference, more importantly it will have a positive impact in your country. By working with INTERPOL, World Customs Organization and an international network of enforcement officers such as the Permanent Forum on International Pharmaceutical Crime, IMPACT aims at improving contact and mutual understanding among enforcement officials of different countries in order to improve coordination of operations and rapid exchange of information. IMPACT is also a platform for enforcement officers to establish communication with health authorities and other stakeholders, including industry and health professionals to combat the trade in counterfeit medical products.

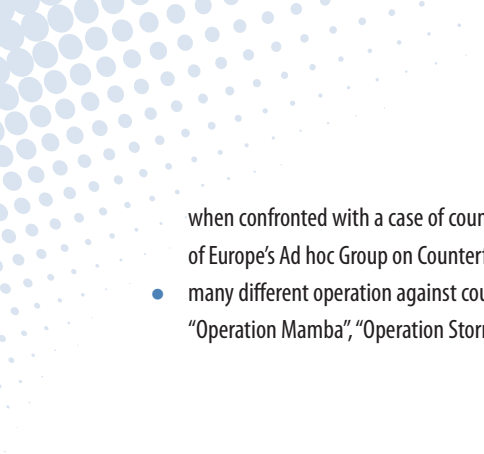
4.1.2 Terms of reference

Currently chaired by Ms Aline Plançon from INTERPOL and Mr Eric McIntosh from Therapeutic Goods Administration, Australia. The Working Group aims to:

- develop advocacy materials to increase resources available for enforcement;
- promote multi-country initiatives to improve coordination and information exchange among enforcement institutions and officers;
- develop projects aimed at improving communication and collaboration between regulatory and enforcement officers;
- develop training materials and manuals to improve skills of enforcement officers;
- identify gaps in existing legislation, need for resources and propose solutions.

4.1.3 Main achievements so far

- developed a guide to investigate counterfeit medical products and pharmaceutical crime. The intent of this guide is to provide processes and techniques to countries developing an investigative capacity to combat counterfeit medicines, in particular identifying, investigating and prosecuting individuals and companies that import, manufacture, supply and export counterfeit medical products into, within and from countries;
- established a "Model for a Network of Single Points of Contact (SPOC)". The aim of this initiative is to facilitate operational collaboration at the international level as well as to streamline collaboration among the different national institutions and other stakeholders involved in investigating, and taking proper timely action



when confronted with a case of counterfeit medical product. This builds upon the work done by the Council of Europe's Ad hoc Group on Counterfeit Medicines;

- many different operation against counterfeit medicines were coordinated at world level, as for example "Operation Mamba", "Operation Storm" and "Operation Pangea" [\[see 4.2 - 4.4\]](#).

4.2 OPERATION PANGEA II INTERNATIONAL INTERNET WEEK OF ACTION

4.2.1 Introduction

For over ten years, the online medicine trade has been universally observed. International actions have been fragmented and usually conducted on a case by case basis. Tackling the issue will not be solved by enforcement action alone but require the public's attention and education as regards to the dangers and increased risks of purchasing medicines on-line.

The Medicines and Healthcare products Regulatory Agency (MHRA) based in the United Kingdom conducted five Internet Days of Action which have resulted in coordinated activity against websites most active in the UK suspected of breaches of medicine regulation, including counterfeit medicines.

In 2008, the Permanent Forum on International Pharmaceutical Crime (PFIPC) organized Operation Pangea, a one-day operation that involved co-ordinated action by Drug Regulatory Authorities of eight countries: Australia, Canada, Ireland, Israel, Singapore, Switzerland, the United Kingdom and the United States of America. Inspections in postal hubs, search warrants and web monitoring led to seizures of thousands of pills and a series of arrests¹. In the frame of the World Health Organization (WHO) International Medical Products Anti-Counterfeiting Taskforce (IMPACT) project, INTERPOL supported the initiative by conveying the results and the public health message to the international community in order to raise awareness.

The intention of Operation Pangea II or "International Internet Week of Action (IIWA)" was to exploit the experience dividend arising from Operation Pangea and to aid the development of a collective and wider partnership approach to combat the trade and sale of counterfeited and illicit medical products worldwide.

Police, Customs services and Drug Regulatory Authorities (DRA) from twenty five countries agreed to participate in the operation. They planned to simultaneously conduct co-ordinated activities against illegal websites selling medicines operating within their respective jurisdictions during the same week.

Operation Pangea II focused on the three essential components that are required to trade illicit and counterfeit medicines through illegal websites: Internet Service Provider (ISP); electronic payment system and mail delivery service.

4.2.2 Objectives

The objectives of Operation Pangea II were the following:

- safeguard public health;
- raise public awareness of the risks of buying medicines from illegal websites;
- seize counterfeit and illegal products, removing them from the market;
- identify the producers and distributors of counterfeit medical products and the criminal networks supporting them;
- close down illegal websites;

- prosecute those responsible and, where appropriate, and seize their assets;
- enhance cooperation between agencies combating the illicit trade in counterfeit and illegal medical products.

4.2.3 Stakeholders

4.2.3.1 National Authorities

Police, Customs services and Drug Regulatory Authorities from 25 countries participated to Operation Pangea II: Austria, Australia, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Lichtenstein, Netherlands, New Zealand, Norway, Poland, Portugal, Singapore, South Africa, Spain, Sweden, Switzerland, Thailand, United Kingdom and United States of America.

4.2.3.2 Intergovernmental Organizations and International Groups:

This initiative was also supported by the World Customs Organization (WCO), the Permanent Forum on International Pharmaceutical Crime (PFIPC), the Working Group of Enforcement Officers (WGEO), OIPC - INTERPOL and Universal Postal Union (UPU).

An Organizing Committee was formed and was composed of: Medicines and Healthcare products Regulatory Agency (MHRA) in the UK, Food and Drug Administration (FDA) and Immigration and Customs Enforcement (ICE) in the U.S., Royal Canadian Mounted Police (RCMP) and Health Canada as well as OIPC- INTERPOL. The Organizing Committee facilitated preparatory steps prior to the operation, the coordination during operation and the post-operation follow-ups. This overall activity was done for the benefit of the WHO's IMPACT programme.

It was decided that INTERPOL will be repository for all daily reports, coordinate follow-ups of actions, provide support to participating countries, collect intelligence and operational results and co-ordinate media coverage. INTERPOL has also provided operational support utilizing the Database on International Intellectual Property (DIIP) Crime to store and process information received from participating agencies. The information gathered during the operation assisted in the creation of this final report to enable results to be diffused amongst stakeholders.

4.2.4 Sequence of events

4.2.4.1 Preparatory phase

In July 2009, the list of countries and organisations taking part in Operation Pangea II was finalized and operational contacts (Single Points Of Contact - SPOCs) were identified from each participating agency.

In August 2009, after using UK developed web crawling software to identify suspicious illicit websites worldwide, the MHRA disseminated intelligence to the countries that had requested searches. In parallel, each country began their own research of suspect websites operating in their country and identified the targets of Operation Pangea II. In September 2009, MHRA collected enforcement activities were due to be carried out by agencies in the participating countries and shared it with the Organizing Committee in preparation.

In October 2009, in order to avoid overlapping in on-going investigations and optimize enforcement actions, key targets were shared with the Pharmaceutical Security Institute (PSI) for checks.

4.2.4.2 Week of Operation

Operation Pangea II started on Monday 16th November 2009 and ended on Friday 20th November. During this week, SPOCs reported to INTERPOL on a daily basis all operational activity together with details of seizures, websites taken-down, raids and arrests. The World Customs Organization connected INTERPOL's SPOCs to their secured Cenn Comm where participating customs agencies reported and exchanged information on seizures.

A team comprising an observer from DRA, a Police and a Customs official gathered in INTERPOL General Secretariat to collectively work in their capacity and to ensure checks, daily reports and follow-ups were complete.

On Thursday 19th November 2009, participating countries, INTERPOL and other relevant International Organizations simultaneously published a common paragraph starting the national press releases. The aim was to increase the number of international recognition and raise the public's awareness.

An internal debriefing session was conducted by MHRA on 27th November 2009 and INTERPOL was invited to share its experience.

4.2.4.3 Post-operation phase

Between December and January 2009, INTERPOL gathered information arising from activities carried out by the participating agencies in order to conclude the final report.

4.2.5 Results

The dedicated week which included web monitoring led to the identification of over 1.200 websites engaged in illegal activity including the sale of suspected counterfeit medicines as well as controlled or prescription only drugs.

237 other websites were closely investigated and 153 of them were shut down.

17 adverts proposing medicines on auction websites were removed.

Law enforcement agencies' action in postal hubs, ports and airports, led to the inspection of over 21.200 packages.

2.356 were seized as they contained counterfeit or illicit pills.

A total of 59 suspects have been identified. At least 12 of them have been arrested and the others are currently under investigation for a range of offences to the illegal sale of pharmaceutical products.

4.2.6 Findings

The range of counterfeit and illicit medicines belongs to wide therapeutic categories. 19 of the 25 countries reported the name of the medicines seized. Analysis of these data leads to the findings below.

The number in brackets indicates the number of times the product has been cited by the participating countries:

- Life-style products as erectile dysfunction medicines and female libido pills [80], have been mentioned 104 times by 17 countries. For weight loss medicines [19], authorities found Reductil and Sibutramine, its active pharmaceutical ingredient. Lida Dai Dai Hua, which claim to be a slimming formula made only from Chinese herbs, was also seized in Switzerland, Belgium and Australia. The last type of life-style products seized is hair loss medicines [5].
- Hormones and steroids have been mentioned 56 times by 10 countries. Human Growth Hormones, Testosterone and anabolic steroids are very popular drugs in the world of bodybuilding. Some diuretics which are included on the World Anti-Doping Agency's banned drug list due to their alleged use as a masking agent for other drugs were also seized during the operation. This may suggest the fact that some competitive sportsmen could also use Internet in order to buy these illegal medicines.
- Narcotics and psychotropic drugs have been mentioned 32 times by 11 countries. They consist mainly of benzodiazepines [12], antidepressant [5] and narcotic analgesic [3] as Vicodin or Codeine.
- Amphetamines and precursors were also seized. In three cases, the precursors have been identified as ephedrine. The similarity in chemical structure to the amphetamines has made ephedrine a sought-after chemical precursor in the illicit manufacture of methamphetamine and methcathinone. Illegal websites are not only distributing counterfeit medicines, they are also involved in the distribution of narcotics and medicines which will be used to manufacture some narcotics. Consequently, it would be interesting to analyze further the potential links between narco-traffickers and counterfeiters.
- Pain killers [12], antibiotics [11], contraceptives, blood pressure medication, anti-fungal were also amongst the medicines seized during Operation Pangea II.

When the origin of the products was reported, it appears that most of the medicines seized at postal hubs were from the country where they were purchased. During web monitoring and investigation on websites, some participating countries analyzed and reported in which country the illicit websites were hosted. At least 41 different countries were identified.

This allows criminals to cover their tracks and make investigations more complex and difficult. After identifying the host country of the website, international collaboration will be essential for law enforcement agencies to manage to shut down the site, notably due to the absence of harmonization between the laws of different countries. Criminals will always try to establish their websites where Internet legislation is weak or permissive.

In several cases, it appears that multiple websites, located in different places and offering medicines to customers from different countries, are associated to the same criminal organization.

- In Austria, law enforcement authorities identified seven illegal websites with the same IP address and hosted by the same provider. Investigation seems to confirm links with Germany and United Kingdom, where a suspect managed a company who owns around 85 domains.

- In Germany, customs are investigating a complex of illicit websites selling pharmaceuticals: at least three different websites could be linked and connections are suspected to link with Italy, United Kingdom and France.

In several countries, authorities seized food supplements or herbal products which were found, after analysis, to contain undeclared active pharmaceutical ingredients (API).

- In Australia, authorities seized some capsules which claim to be natural herbal formulas for weight loss but which contain in fact an important dose of Sibutramine, the active pharmaceutical ingredient (API) of weight loss medicines which can only be supplied on a doctor's prescription.
- In Israel, some food supplements were found to contain also Sibutramine or Sildenafil (API for erectile dysfunction medicines).
- In New Zealand, seven consignments of products purporting to be purely herbal were found to contain undeclared western medicines. Finally, in Singapore, most of the packages seized contained health products suspected of being adulterated with western medicines.

Patients with allergies, high blood pressure, heart problems, kidney diseases or who are pregnant could suffer serious side effects. This can be aggravated by the fact that the API added discretely in so-called "natural" products can be over dosed. In Australia, some capsules were found to contain 24.1mg of Sibutramine while the genuine product contain only between 10 and 15mg of the same active pharmaceutical ingredient.

This problem should be taken very seriously as it has increased significantly over the last two years. Undeclared API mixed with herbal products has already engendered several deaths, notably in Singapore, Hong Kong and France².

4.2.7 Recommendations

All the countries and International Organizations that have participated in Operation Pangea II have expressed their willingness to take part in a similar operation in 2010. However, some recommendations have been identified in order to improve results of Pangea III.

One of the positive outcomes of Operation Pangea II was enhanced cooperation among police, customs and drug regulatory authorities. However, there is still a need for better coordination of activities as well as an improved exchange of information between the different stakeholders: national agencies, international organizations and the International Internet Week of Action Organizing Committee.

The list of participating countries as well as the list of national Single Points of Contact (SPOCs) should be established further in advance to allow different agencies within the same country to coordinate their action and start to gather intelligence at least one or two months before the official date of the operation. The involvement of police, customs and INTERPOL National Central Bureau (NCB) should also be improved.

The date and time of the press release should be discussed amongst all participating countries, to take into account the time difference between regions, to facilitate planning of activities internationally, in order to avoid the early release of information and to gain the best and most widespread media coverage.

The incident reporting form needs to be more complete to include notably the exact amount of pills seized (a package can contain 10 pills or 100.000 pills), the estimated retail value, the country of origin of the products, the type of illegal medicines (unregistered, counterfeit, herbal products containing active pharmaceutical ingredients). Providing

more details would allow to increase knowledge in terms of risk analysis and to identify more trends related to the illegal sale of medicines over the Internet.

With the NCB playing a more active role, more nominal information could be exchanged so that the coordinating team can make the initial searches and can start the international assistance. Sharing information with INTERPOL on the names of suspects, websites, locations, email addresses and phone numbers, will allow additional searches in specific databases and increase the probability finding links with other countries or former criminal circles.

More countries should be encouraged to join Operation Pangea III, notably from regions which were under-represented this year, such as South America, Eastern Europe, Asia or Africa. The international media coverage on Operation Pangea II was also an opportunity to raise awareness amongst the law enforcement authorities in charge of this problem. After the Operation, several countries or agencies, as Japan or Norway customs, demonstrated their interest to participate to the next operation of this type.

Increasing cooperation with the World Customs Organization will allow greater involvement of Customs Services from more countries and will facilitate the transmission of information between different agencies.

Specific cooperation could be developed on the financial aspect of the criminality, notably with private companies such as Amex, Paypal or Visa.

In future, some other partnerships may help to improve the results of the operation. For instance, Microsoft approached INTERPOL-IMPACT to offer its technical support and expertise during the next enforcement phase. The Universal Postal Union (UPU) will also increase its involvement.

The Organizing Committee may consider involving the private sector in order to get supplementary intelligence and legal support during the operation.

Finally, as raising awareness is a key factor, the Committee will consider working on a basis of raising awareness campaign that can be developed by each country according to the needs to educate the public in a clear and active manner.

4.2.8 Media Coverage

The main objective of Operation Pangea II was to safeguard public health notably by raising public awareness of the risks of buying medicines from unregulated and illegal websites. Use of media and expansion of its coverage constituted a crucial point of the operation.

All stakeholders involved in the operation agreed on a common introductory paragraph to be integrated into the press release the 4th day of Operation Pangea II. The rest of the press release was left to participants to detail their specific activity. The simultaneity of the press release as well as the common message led to massive international media coverage.

After Operation Pangea II, a feedback form was sent to the participating countries by the IIWA (International Internet Week of Action) Organizing Committee, asking what kind of media coverage was done. The Internet and newspapers were the two main media sources in relaying results of Operation Pangea II, before radio and television. Most of the coverage emphasized the threat to public health from obtaining medicines from unregulated websites.

A search made on the term "Pangea II" by Meltwater News, a company which tracks over 100.000 global news sources in 110-plus countries and 50-plus languages, demonstrated that hundreds of articles have been published on the

operation. Most articles were published by European or North American websites, even if they can be accessed by readers in any part of the world.

The accessibility of the information was also increased by the fact that the articles were published in at least 17 different languages:

4.2.9 Conclusion

The results of Operation Pangea II have been impressive, in terms of multi-agency and multi-country involvement, the number of websites identified and shut down and the amount of packages inspected and seized. Overall, the massive media coverage allowed millions of potential customers to note the dangers encountered when buying medicine over the Internet. Collaboration within each country but also at the international level remains the key success factor in disrupting this international criminal activity which jeopardizes health and lives.

The partnership and collaboration with customs and police was a key element for the success of this International Internet Week of Action but also a strong step forward to establish a more regular working relationship throughout the year between the different agencies. However, the operation will maintain its focus on public health, which is the responsibility of the national drug regulatory authorities of the participating countries.

4.2.10 Notes

¹*Interpol Media release, illegal online medicine suppliers targeted in first international Internet day of action, november 13, 2008,*

www.interpol.int/Public/ICPO/PressReleases/PR2008/PR200863.asp

²*France : Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), Mise en garde sur les gélules « Best life », November 6, 2008,*

<http://afssaps.sante.fr/htm/10/filcoprs/cp bestlife 112008.htm>

Hong Kong: The Standard, Alarm over killer impotence drugs, Nickkita Lau and Patsy Moy, February 6, 2008,

http://www.thestandard.com.hk/news_detail.asp?pp_cat=11&artid=61245&sid=17462205&con_type=1

Singapore : Shanghaiist, 10 men in Singapore die from illegal China made sex pills, November 2, 2008,

http://shanghaiist.com/2008/11/02/10_men_in_singapore_die_from_illega.php

4.3

OPERATION PANGEA III INTERNATIONAL INTERNET WEEK OF ACTION

[October 2010]

4.3.1 Introduction

Operation PANGEA III took place as an International Internet Week of Action (IIWA) between 5th and 12th October 2010 involving 45 countries with Police, Customs and Regulatory Authorities responsible for the enforcement of medicines and medical devices. This was the third and largest international operation of its kind, following Operations PANGEA I and II respectively.

As in Operation PANGEA II, the intention of Operation PANGEA III or the “International Internet Week of Action (IIWA)” was to exploit the experience dividend arising from the successful Operations PANGEA and PANGEA II and to aid the development of a collective and wider public-private partnership approach to combat the trade and sale of counterfeit and illicit medical products worldwide.

4.3.2 Purpose

The main purpose of this Operation was to use enforcement action as the lever to inform the public of the increased risks to their health from obtaining medical products through unregulated websites.

4.3.3 Objectives

The objectives of Operation PANGEA III in safeguarding public health were to:

- raise public awareness of the risks of buying medical products from illegal websites;
- identify the producers and distributors of counterfeit medical products and the criminal networks supporting;
- remove payment providing facilities from those illegally supplying illegal and counterfeit medicines;
- seize counterfeit and illegal products, removing them from the market;
- close down illegal websites;
- prosecute identified offenders.

4.3.4 Operational approach

The three main components abused by people seeking to make a profit in this illegal website trade were targeted – the Internet Service Provider (ISP), electronic payment system and the delivery service.

PANGEA III was assisted further by the electronic payment industry focusing on the abuse of the electronic system.

4.3.5 Participants in Operation PANGEA III

National Authorities

Police, Customs services and Medicines Regulatory Authorities from 45 countries participated:

Angola, Australia, Austria, Azerbaijan, Belgium, Brazil, Bolivia, Canada, China, Colombia, Croatia, Cuba, Czech Republic, Denmark, Estonia, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Jordan, Malta, Mexico, Netherlands, New Zealand, Northern Ireland, Norway, Poland, Peru, Portugal, Romania, Russia, Singapore, Slovak Republic, South Africa, Spain, Sweden, Switzerland, Thailand, United Kingdom, Uruguay and United States of America.

Intergovernmental Organizations and International Groups:

This initiative was also supported by the OIPC – INTERPOL, World Customs Organization (WCO), the Permanent Forum on International Pharmaceutical Crime (PFIPC), the Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO).

Industry

Supporting the initiative from the pharmaceutical industry was coordinated by the Pharmaceutical Security Institute (PSI); and the Electronic Payment Industry with active participation this year from Visa.com, MasterCard, BarclayCard, PayPal and Western Union.

An Organizing Management Committee was formed and was composed of:

- Food and Drug Administration (FDA) and Immigration and Customs Enforcement (ICE) of the U.S.A
- Medicines and Healthcare products Regulatory Agency (MHRA) in the UK,
- OIPC- INTERPOL,
- Pharmaceutical Security Institute
- Royal Canadian Mounted Police (RCMP) and Health Canada (HC) in Canada
- Irish Medicines Board (IMB) in Ireland
- World Customs Organisation (WCO)

The Organizing Management Committee

- Provided the overall planning and liaison for the operation, the coordination during operation and the post-operation follow-ups.
- INTERPOL provided the repository for all daily reports, coordinated follow-ups of actions, provided support to participating countries through their I-24/7 System, collected intelligence and operational results and co-ordinate the media coverage.
- The World Customs Organization SPOCs connected to their secured Cenn Comm where participating customs agencies reported and exchanged information on seizures and reported information to INTERPOL's team.
- This overall activity was done for the benefit of the International Medical Products Anti-Counterfeiting Task-force (IMPACT) programme.

4.3.6 Overall results

On an international scale the outcome was considered to be unprecedented and therefore a great success:

- 278,000 packages were inspected globally by regulators and customs throughout the week long operation;
- 11,349 packages were detained;
- 2.300,000 tablets were seized in total;
- Product types seized related to erectile dysfunction pills, weight loss tablets, antibiotics, hormones, anabolic steroid containing products, anti-depressants, pain-killers, cardiac medication, anti-cholesterol, stimulants/ amphetamines, cancer medication and insulin;
- 335 portal hubs were inspected for illegal activity;
- 130 warrants were executed;
- 822 websites identified as engaging in illegal activities;
- 297 websites shut down and 30 adverts removed;
- 10 awareness campaigns;
- 87 individuals arrested and currently under investigation in relation to a range of offences, including illegally selling and supplying unlicensed or prescription-only medicines;
- US\$ 6.77 million in value of seized illegal and counterfeit medicines;
- 44 countries participated in Operation Pangea III, up from 25 in Operation Pangea II.

4.3.7 Media coverage

- Safeguarding public health notably by raising public awareness of the risks of buying medicines from unregulated and illegal websites, through enforcement activity, was the main objective of the operation. This was primarily carried out through the print and social media.
- Operation PANGAEA III's approach, as with PANGAEA II, was to agree on a common introductory paragraph available for all participating agencies to use by integrating into their own media release on the agreed date of 14th October 2010, two days following the completion of the operation. INTERPOL's website published this common introductory paragraph. The participants completed the remainder of the media release to outline how they operated and reflected their successes in their respective jurisdictions and areas.
- The simultaneity of the press release as well as the common message led to massive international media coverage.
- With the support of the Organising Committee INTERPOL launched an advertising campaign online on its Youtube account, called "Don't be your own Killer" and relayed basic information on the dangers of buying medical products online.

4.3.8 Conclusion

- The recommendations made following Operation PANGAEA II have been acted upon, in particular the increasing country participation and active involvement of the Electronic Payment industry to disrupt and cut off payments from unsuspecting customers to criminals abusing their electronic payment systems.
- Greater cooperation at national level between medicines regulatory authorities, customs and police raised the profile of the operation nationally and provided dividends in support of public health.
- A greater concentration on website take down has resulted in disrupting the facility for criminals hiding from the consuming public as well as from authorities.

- Collaboration within each country but also at the international level remains the key success factor in disrupting this international criminal activity which jeopardizes health and lives.
- A greater awareness among the public of illegal and unregulated websites selling illegal and counterfeit medicines and the dangers presented therein.
- A greater willingness for authorities to cooperate nationally and internationally by joint planning and operations in future years.

4.4 OPERATION STORM II

[January 2010]

4.4.1 Introduction

Counterfeit medical products pose a major risk to public health and are becoming increasingly prevalent in all parts of the world, particularly in South East Asia.

Under the framework of the World Health Organization's (WHO) International Medical Products Anti-counterfeiting Task Force (IMPACT), Operation Storm II (July-November 2009) was co-ordinated by INTERPOL and supported by the Western Pacific Regional Office (WPRO) of WHO.

4.4.2 Objectives

The objective of Operation Storm II was to build on the success of Operation Jupiter South East Asia and Operation Storm, previously carried out in the region.

Operation Storm II aimed to develop a multi-dimension partnership approach by, the police customs and national drug agencies in the affected countries, to disrupt the activities of transnational organized criminals involved in the trafficking of counterfeit medical products in Great Mekong Area and to enhance the partnership with the private sector.

The intention of Operation Storm II was also to reinforce the expertise in investigating counterfeit medical products, focus on single or groups of counterfeit medicines in South East Asia and turn the existing partnership between police, customs and national drug regulatory bodies into concrete action.

4.4.3 Methodology of Operation Storm II

Stakeholders

Operation Storm II provided a platform for collaboration between national police, customs and drug regulatory authorities from eight countries: Cambodia, China, Indonesia, Laos, Myanmar, Singapore, Thailand and Vietnam. Single Points of Contact (SPOCs) were identified to assist this meeting and to take part into the operation.

Two laboratories, the Health Sciences Authority (HSA) of Singapore and the Counterfeit Drug Forensic Investigation Network (CODFIN), funded by the Gates Foundation, provided forensic support during the operation.

Private sector companies also provided additional inputs, notably by sharing intelligence with the participating countries.

Operation Storm

The Operation was coordinated by INTERPOL, with the support of the National Central Bureau (NCB) and the Liaison Office Bangkok (LOBANG) and supported by the Western Pacific Regional Office (WPRO) of World Health Organization (WHO).

Operational Plan

Operation Storm II took place during five months, from July to November 2009.

INTERPOL organized a planning meeting in Bangkok, Thailand in the lead up to the overt phase of Operation Storm II. A second planning meeting was planned but has been cancelled due to the swine flu pandemic. During the planning meeting, it was decided to target medicines primarily taken as remedies for life threatening diseases as well as common counterfeit medicines found in the South East Asia:

- Anti-malaria
- Anti-Tuberculosis
- Anti- HIV
- Antibiotics – pneumonia and child-related illnesses
- Antivirals (Tamiflu type)
- ED Drugs (Viagra type)

Several types of enforcement activities were discussed, notably:

- Development of already existing cases
- Build-up on intelligence cases : assessment of the national situation
- Pharmaceutical market investigation
- Intelligence from the private sector
- Specific inspections
- Intensive checks
- Internet related activities

A final meeting has been held in January 2010, in Yogyakarta, Indonesia, to evaluate the results, discuss the recommendations and the way forward.

Pharmaceutical Market Surveillance and forensic analysis

A component of Operation Storm II was to carry out pharmaceutical market surveillance in participating countries in order to enhance field intelligence which will aid future enforcement actions.

The Gates Foundation through the ACT Consortium set up a network, Counterfeit Drug Forensic Investigation Network (CODFIN), to facilitate the forensic chemical and biological analysis of suspected poor quality antimalarials and the dissemination of this information. During Operation Storm II, 78 samples of antimalarials plus co-trimoxazole antibiotics were sent to CODFIN for testing. No counterfeit medicines were detected but the difficulties of obtaining genuine packaging means that analysis was uncertain for many samples. However, a considerable problem of apparent substandard or degraded medicines was identified with 51% of all samples containing at least 1 tablet with <90% or >110% of active pharmaceutical ingredient (API) present, in comparison to that stated on the packet or collection bag.

The Health Science Authority (HSA) Laboratory in Singapore analysed 106 samples of Antibiotics, Erectile dysfunction drugs, Anti-obesity, antimalarials, vitamins, anti-ulcers and antipyretic analgesics. Both counterfeit and substandard medicines were identified.

Refer to Appendix A for detailed results of the analysis.

Support from the Private Sector

Operation Storm II included the inputs of the private sector which were willing to supplement intelligence and to assist in developing cases.

During the planning meeting in Bangkok, Thailand, in July 2009, several pharmaceutical companies shared intelligence concerning the trade of counterfeit medicines. Notably, some names and addresses of pharmacies and market places suspected to sell illegal medical products were given to the participating agencies to become a target. They have also provided some information on specific products which are very prone to be counterfeit.

At the Operation Storm II final meeting in Yogyakarta, the private sector was represented by the Pharmaceutical Security Institute (PSI), a not-for-profit, membership organization dedicated to protecting the Public Health, sharing Information on the Counterfeiting of Pharmaceuticals and initiating Enforcement Actions through the Appropriate Authorities.

Pharmaceutical companies recognize the great impact of being involved in the Operation Storm Network to fight counterfeit medical products. They are willing to provide assistance in identification of counterfeit medicines.

When information are provided by the various countries (as the name of the products seized, location where the medicines were found, person arrested or being investigated, . . .), PSI and the pharmaceutical companies can follow up with the counterfeit problem and cases.

PSI also wishes to provide more intelligence to help countries in their investigation and to support them in enforcement training. PSI can also arrange the buying of samples needed to be test and make the link with the companies concerned to offer the initial examination of the drugs seized.

Lines of Communication

The national agencies were encouraged to share intelligence among them but also with the INTERPOL National Central Bureau (NCB) and the INTERPOL Liaison Office Bangkok (LOBANG) in Thailand.

The INTERPOL coordinating team communicated with each NCB during and after the operation. Additionally, the INTERPOL coordinating team and the national agencies have also exchange intelligence with the private sector.

With the support of Interpol's Regional Bureaus, National Central Bureaus and private sector representatives, two INTERPOL-IMPACT Enforcement Training were organized.

These training sessions catered for officials from police, customs, and national drug regulatory agency that have basic or no experience dealing with crime involving counterfeit pharmaceuticals. Trainees also received a manual prepared by the Permanent Forum on International Pharmaceutical Crime (PFIPC).

These sessions typically ran for two days, and included scenario trainings, counterfeit identification and samples handling techniques. These training courses provide general facts on counterfeit medical products and specific investigative methodologies that will allow enforcement agencies to disrupt the manufacture, trade and distribution of counterfeit medicines in their country.

The training sessions were held in Bangkok, Thailand on 14 and 15 July 2009 and in Jakarta, Indonesia on 25 and 26 January 2010. Up to 70 personnel from the different national law enforcement agencies (Police, Customs, Drug Regulatory Authorities. . .) were trained.

Raising Awareness

At the end of the operation, each country organized simultaneously a national press conference to disclose the national and regional figures and to raise awareness by delivering a common message emphasizing that counterfeit medical products harm and can lead to death and that organized criminals are crossing the borders to smuggle counterfeit medical products and illicit medicines.

A press media release on the results of Operation Storm II and the creation of the Storm Network was also published by INTERPOL.

4.4.4 Final Results

Operation Storm II led to the seizure of 20 million pills of medicines, including antibiotics, anti-malarial and birth control medicines, anti-tetanus serums, Aspirin and erectile dysfunction drugs: over 12 million pills of counterfeit medicines and medical products were seized, as were nearly 8 million pills of other illegal medicines (expired, not registered or diverted medical products).

It also led to the closure of more than 100 pharmacies and illicit drug outlets and to the arrest of at least 33 suspects.

4.4.5 Recommendations

Stemming from the challenges above, some global recommendations were made for the next operations in the region.

Creation of Storm Network

The group decided to consolidate its existing network by formalizing it into a “Storm Network”. Based on the existing model for a Network of Single Points of Contacts (SPOCs) forming the Operation Storm I and II group, the network will get terms of reference and will develop the continuous exchange of information among its members as well as raising awareness.

Countries suggested extending the Storm Network to countries that didn't participate in Operation Storm I and II as Philippines, Malaysia and India. It was also agreed that the World Customs Organization will be fully part of the Storm Network.

The Storm Network will focus mainly on three types of activities:

- enforcement actions;
- forensic investigations and laboratory extension;
- raising public awareness.

Other recommendations from the participating countries

- strong and clear support from top levels;
- creation or reactivation of national multi-agencies committee to combat counterfeit medicines;

- enlarging the scope of the targets;
- improvement of law enforcement;
- concrete actions amongst agencies;
- exchange of information among Single Points of Contact (SPOCs) more consistent, regular and efficient;
- exchange of information with INTERPOL more systematic;
- find common procedure to send samples for analysis through INTERPOL Liaison Office Bangkok (LOBANG)
- legal status and use of Health Sciences Authority (HAS) and Counterfeit Drug Forensic Investigation Network (CODFIN) analysis of samples;
- continuous samples investigations to HSA up to 70 samples/month – send packaging as well;
- creation of integrated trainings;
- need for raising awareness to public and also to justice;
- raising funding to support enforcement activities;
- need a secure system for information/intelligence exchange;
- HSA-INTERPOL agreement to set up Service Excellence Centre to provide training on counterfeit medical products in the region.

4.4.6 Conclusion

Once again, Operation Storm II has shown the importance of the collaboration and the coordinated action among police, customs and national drug regulatory agencies in combating counterfeit medical products in the field. Working at a regional level also allows the countries to share their experience on the criminal aspects and the products readily counterfeit. This leads to an improvement of intelligence gathering at a national level and, consequently, and affects very positively the results of the Operation.

During Operation Storm II, the participating countries improved their capacity to combat counterfeit medical products and reported many complex investigations leading to success story.

Market surveillance operated by regulatory reveals the level of counterfeit or potential counterfeit medicines on the market which is very concerning. This forensic investigation is both linked to the evidence gathering and to tropical disease resistance that hits the Asian continent.

The decision by the participating countries to create a “Storm Network” in collaboration with Western Pacific Regional Office (WPRO) of WHO will improve and shape joint anti-counterfeit actions on an on-going basis in the region.

4.4.7 Appendix A | Results of the forensic analysis

Results from the Health Science Authority (HSA)

The Health Sciences Authority (HSA) Laboratory in Singapore has provided scientific analysis of 106 samples collected in five participating countries: Thailand (47 samples), Cambodia (35 samples), Lao PDR (19 samples) and Singapore (5 samples).

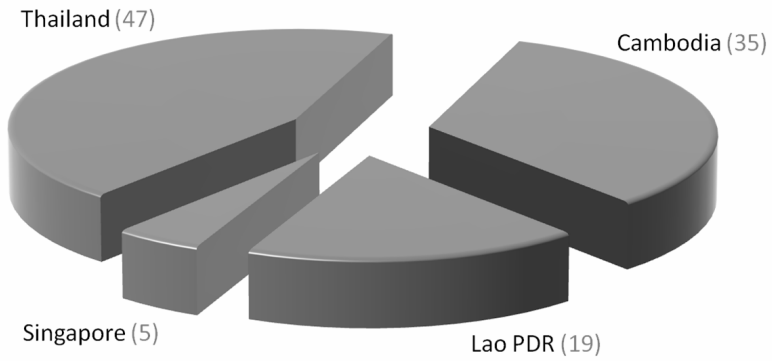


Fig. 1 Distribution of samples by countries.

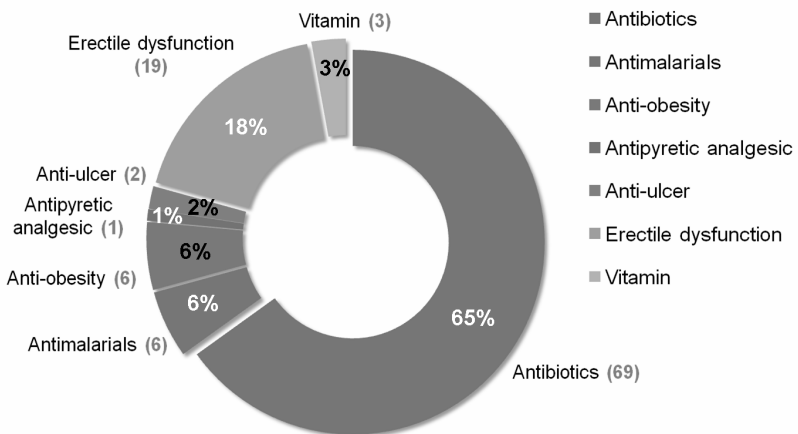


Fig. 2 The samples collected belong to seven different therapeutic categories.

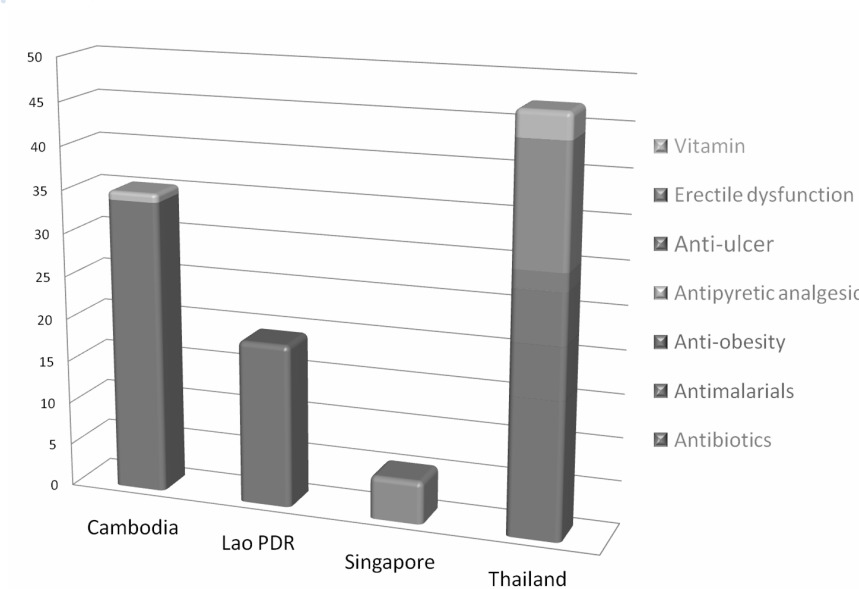


Fig. 3 Distribution of samples based on countries and drug classes

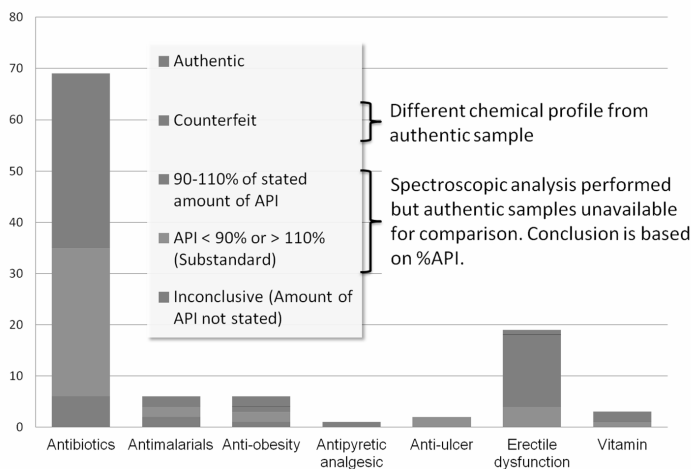


Fig. 4 The analysis of the medicines was mainly based on the amount of Active Pharmaceutical Ingredient. Due to the lack of authentic sample for comparison, only few medicines have been identified as “counterfeit” or “genuine”.

Concerning the anti-obesity medicines, 6 samples from Thailand were analyzed, comprising 4 types of anti-obesity drugs and 2 types of active ingredients. Half of the samples were generics (containing Sibutramine) and half were branded products (Xenical, Roche).

For the generics, there was no authentic sample for comparison. Consequently, it was impossible to determine if the products were counterfeit or genuine. However:

- 2 samples were substandard
 - One was containing 70-90% of stated amount of Active Pharmaceutical Ingredient (API)
 - One was containing over 110% of stated amount of API
- The third sample did not state the amount of API on packaging

TRADE NAME	API	MANUFACTURER	RESULTS CONCLUSION
Sibutramine hydrochloride	sibutramine hydrochloride	Shangai Modern Pharmaceutical Co., Ltd	substandard (70-90% of stated amount of API)
Sibutramine	sibutramine	not stated	amount of API not stated, 16 mg/cap sibutramine
Reduce-15 mg	sibutramine hydrochloride	Kniss Laboratories Pvt. Ltd	(>110% of stated amount of API)

TRADE NAME	API	DECLARED API AMOUNT (mg)	SAMPLE	%API	CHEMICAL PROFILE
Xenical	Orlistat	120	1	98	Different profile from authentic
			2	96	Similar profile as authentic
			3	98	Similar profile as authentic

For the Xenical samples, chemical assay conforms to standard of 90-110% API, however, that does not mean the product is genuine. In one case, the chemical profile was not the same as authentic: excipients were different, and of unknown quality.

For the Sample n°1, some differences with the authentic product and the sample were observed, notably on the blister packs:

- Different in design, printing and colour
- Poorer printing quality compared to authentic

trade name	API	no. of samples	results
Cialis	Tadalafil	2	all counterfeits
Viagra	Sildenafil	7	all counterfeits, except 1
Coverta	Sildenafil	5	2 samples within 90-110%API, 3 substandard (2: 70-90% API, 1: > 110% API)
Elonza 100	Sildenafil	1	substandard (super potent, >110% API)
Mastigra 100	Sildenafil	3	all within 90-110% API; different chemical profile from Viagra
Religra 100	Sildenafil	1	90-110% API

Concerning the erectile dysfunction (ED) medicines, 19 samples from Singapore and Thailand were analyzed: 2 Cialis, 7 Viagra, 5 Caverta and 5 Sildenafil products of different trade names.

8 samples were found to be counterfeits and 4 samples were substandard. Concerning the antibiotics, 69 samples from Cambodia, Lao PDR and Thailand were analyzed comprising 14 amoxicillin, 15 ampicillin, 21 tetracycline, 9 phenoxymethylpenicillin, 6 ciprofloxacin and 4 other types of antibiotic APIs.

One sample was concluded as counterfeit because its API was stated as ampicillin, however it contains amoxicillin.
29 Samples were substandard as they contain less than 90% of API or over 110%.

results conclusion	no. of samples
counterfeit (wrong API)	1
API within 90-110%	33
API < 90% or >110% (substandard)	29
inconclusive (amount of API not stated)	6

The following manufactures were identified as producing substandard antibiotics

manufacturers	API	trade name	%API
CHEA CHAMNAM laboratoire Co, LTD	phenoxymthylpenicillin (pen V)	SQUASH	70-90%
Codupha	amoxicillin-ampicillin	amoxicillin-ampicillin	70-90% 50-90%
E.K.H Co., LTD	ampicillin	ampicillin	70-90%
Flamingo Pharmeceuticals LTD	ampicillin	ampicillin	70-90%
Fu Li Pharmaceutical China	ampicillin	AMPIMEX -500	<50%
KPN Pharma Factory	Tetracycline	Herolmycin	80-90%
Masa Lab	Tetracycline	CONFIT	70-90%
Medical Supply Pharmaceuti- cal Enterprise (MS)	Cloxacillin	CLOXA MS 500	50-70%
P.D.C.	ampicillin	AMPICILLIN	70-90%
T.MAN PHARMA LTD., PART	Tetracycline	BIOMAN	70-90%
Zhangfen Pharmaceutical Factory, Longchuan, Yunnan, China	ampicillin	ampicillin	50-70%

4.4.8 Results from the Counterfeit Drug Forensic Investigation Network (CODFIN)

In October 2009 a series of 78 samples of antimalarials, plus co-trimoxazole antibiotics, were received for analysis by the Counterfeit Drug Forensic Investigation Network (CODFIN). A sample is defined as a group of apparently identical dosage units (eg tablets or vials) sold at the same time from the same outlet. These were seized by law enforcement agencies in South East Asia as suspect counterfeits. The collection consisted of:

- Artesunate tabs 30 (labelled as made by 4 companies)
- Artesunate iv/im 1 (labelled as made by 1 company)
- Artemether capsule 1 (labelled as made by 1 company)
- Dihydroartemisinin-piperazine tabs 3 (labelled as made by 1 company)
- Artesunate+mefloquine tabs 3 (labelled as made by 2 companies)
- Quinine tabs 10 (all loose, no labelling)
- Quinine iv/im 6 (labelled as made by 1 company)
- Chloroquine tabs 16 (all loose except 1)
- Sulphadoxine-pyrimethamine tabs 4 (labelled as made by 2 companies)
- Co-trimoxazole tabs 4 (labelled as made by 3 companies)

Attempts have been made to obtain genuine examples, direct from the companies concerned, for the samples with packaging.

25/26 chloroquine and quinine samples consisted of tablets loose in plastic bags without any manufacturer's information.

Of the oral chloroquine 13/16 (81%) samples contained at least 1 tablets with chloroquine content >110% than that stated.

Of the oral quinine 9/10 (90%) of samples contained at least 1 tablet with quinine content <90% than that stated. All 6 quinine iv contained between 90-110% of the content stated on the vial as did the one sample of parenteral artesunate.

Of the 4 samples of sulphadoxine-pyrimethamine (SP) 2 (50%) samples contained at least 1 tablets containing <90% of stated sulphadoxine content and 3/4 (75%) contained at least 1 tablets containing <90% of stated pyrimethamine content. Overall all 4 SP samples failed content analysis. Dissolution tests were not performed.

Four samples of the antibiotic sulfamethoxazole-trimethoprim were also received. All failed content analysis which each sample containing at least 1 tablets with sulfamethoxazole and trimethoprim content <90% of that stated on the packaging.

Of the oral artesunate, 4/30 (13%) samples contained at least 1 artesunate tablets with content outside 90-110% of that stated on the packet. Of artesunate labelled as manufactured by Binh Dinh Pharma 2/7 failed (with <90% AI), of artesunate labelled as manufactured by Mekophar 1/13 failed (with >110% AI) and of artesunate labelled as manufactured by Medical Supply Pharmaceutical Enterprise 1/8 failed (with >110% AI).

All 3 dihydroartemisinin (DHA)-piperazine samples contained at least 1 tablet with DHA content <90% of that stated whilst none contained at least 1 tablet with piperazine concentrations outside the stated range. Alarmingly the packet of this product bore the text '2 days malaria treatment' whilst the available evidence suggests that a minimum of a 3 day course is required for malaria treatment. Of the three artesunate+mefloquine samples, all contained at

least 1 tablet with less than 90% of the stated amount of artesunate. Only one sample contained mefloquine tablets – these tablets had been cut off the other co-blister packs of artesunate+mefloquine before delivery to CODFIN.

No spelling or other errors, which might suggest counterfeiting, were noted. By comparison with the genuine samples available for CODFIN, no evidence was found of counterfeiting for the STORM II samples. The other companies, stated as producing the other products, have been written to but we have so far had no response.

No counterfeit medicines were detected but the difficulties of obtaining genuine packaging means that analysis was uncertain for 38/53 (72%) of those with packaging and the absence of any packaging with the tablets means that analysis was uncertain for 25/78 (32%).

A considerable problem of apparent substandard or degraded medicines was identified with 40/78 (51%) of all samples containing >1 tablet with <90% or >110% of active ingredient present, in comparison to that stated on the packet or collection bag, especially for artesunate tablets, DHA-piperaquine tablets, artesunate+mefloquine, quinine tablets, SP tablets and sulfamethoxazole-trimethoprim tablets. It is not possible to distinguish whether those containing less than the stated amount of active ingredient were substandard or degraded.

These results are of great concern for malaria control as the medicines containing lower than the expected active ingredient concentrations are likely to be sub-therapeutic and to engender antimalarial drug resistance. There is also of concern that artesunate tablets in packs of monotherapy were collected as these are no longer recommended by WHO for the treatment of uncomplicated falciparum malaria, except in special circumstances. The finding of a product stating that it is a '2 days malaria treatment' is also of great concern as there is no evidence that we are aware of to support this dosage claim.

4.5

OPERATION MAMBA III

[July-August 2010]

A combined international operation across East Africa targeting counterfeit medical products and pharmaceutical crimes has resulted in the seizure of at least 10 tons of counterfeit and illicit medical products and more than 80 arrests of individuals suspected of involvement in the illegal manufacture, trafficking or sale of counterfeit and diverted medical products.

Involving police, customs and drug regulatory authorities across Burundi, Kenya, Rwanda, Tanzania, Uganda and Zanzibar, Operation Mamba III (July-August 2010) was co-ordinated by INTERPOL and undertaken under the umbrella of the World Health Organization's (WHO) International Medical Products Anti-Counterfeiting Taskforce (IMPACT). Forensic assistance was provided by the laboratories of the Singaporean Health Science Authority, and the operation also included support from the World Customs Organization. It was the third such operation in as many years aiming to curb the manufacture and distribution of counterfeit medical products in East Africa.

The head of INTERPOL's Medical Products Counterfeiting and Pharmaceutical Crime (MPCPC) unit, Aline Plançon, said that stemming the tide of fake, dangerous and diverted medical products required close collaboration between the health sector, law enforcement, international organizations and non-governmental organizations. She encouraged in this area 'the development of a more systematic exchange of information to pool expertise, experience, resources, intelligence and technical support'.

"Operation Mamba III demonstrates that by working together collectively, countries can take concrete action on the ground to curb a crime that is still low-risk and high-profit for the criminals involved while representing a very real danger to the general public."

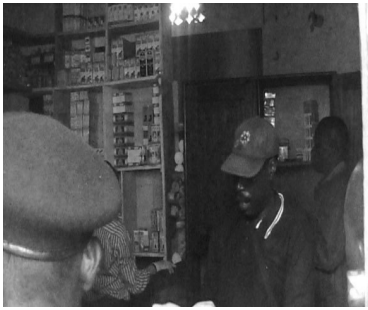
The two month-long operation saw some 300 premises checked or raided across the participating countries and investigations are still on-going following the seizure of counterfeit essential medicines such as vaccines, anti-malaria drugs and antibiotics. Law enforcement agents also seized significant quantities of government medicines that were diverted to illegal re-sale markets.

With counterfeit and unregulated medical products becoming increasingly prevalent, sophisticated and dangerous to the public worldwide, particularly in Africa, "Operation Mamba III will also have served as a necessary platform to build up the awareness, resources and educational efforts which will play an essential role in making significant progress against counterfeiters in the coming years," continued Aline Plançon, adding that the East African Community Secretariat had a key regional role to play in this respect.

Representatives of the participating countries will meet in Zanzibar next week (1-2 September) in order to review and draw on the results of Operation Mamba III, and to further harmonize the region's approach against counterfeit and unregulated medical products.

<http://www.interpol.int/Public/ICPO/PressReleases/PR2010/PR065.as>

East Africa's Zanzibar Declaration to boost fight against counterfeit medical products and pharmaceutical crimes



figs. 1&2 East Africa's Operation Mamba III targeted the manufacture and distribution of fake, dangerous and diverted medical products through collaborative action. The operation also aimed to raise awareness, resources, educational efforts and capacity building on the issue, including through seminars.

A meeting involving East African countries which recently participated in Operation Mamba III targeting counterfeit medical products and pharmaceutical offences has unanimously endorsed a declaration to further harmonise the region's approach against such crimes through closer co-operation with international law enforcement.

Under the Zanzibar Declaration, national and regional authorities will closely partner INTERPOL and other stakeholders such as the World Customs Organization (WCO) to establish national joint taskforces to fight counterfeit medical products and other pharmaceutical crimes. The declaration also calls for better use of existing networks to obtain and share information on suspects and suspected companies, in particular INTERPOL's I-24/7 global police communications system; for more targeted and intelligence-led operations; and for greater public awareness on the dangers posed by counterfeit medical products.

Participating countries at the two-day meeting (1-2 September) also expressed their support for the World Health Organization's (WHO) International Medical Products Anti-Counterfeiting Taskforce (IMPACT), especially its enforcement component.

"The unanimous adoption of the Zanzibar Declaration represents a significant step forward in the fight against medical products counterfeiting and pharmaceutical crimes across East Africa and serves as a model for other regions worldwide. It shows how bridges can be built between different agencies and national authorities to formulate a stronger enforcement response to

these unacceptable criminal acts," said the head of INTERPOL's Medical Products Counterfeiting and Pharmaceutical Crime (MPCPC) unit, Aline Plançon. Officials at the Zanzibar meeting included the heads of INTERPOL's National Central Bureaus in Burundi, Kenya, Rwanda, Tanzania and Uganda, as well as senior national Criminal Investigation Department police officials, heads of regulatory authorities, heads of customs from those countries and Zanzibar, and representatives from the East Africa Community Secretariat, WHO national representatives and the WCO Regional Liaison Office Bureau.

The event brought together the countries and international agencies which participated in Operation Mamba III (July-August 2010), an East African operation which netted some 10 tons of seized counterfeit and illegally diverted medical products and led to more than 80 arrests of individuals suspected of involvement in the illegal manufacture, trafficking or sale of such products.



5

**WORKING GROUP
ON REGULATORY
IMPLEMENTATION**

5.1 OVERVIEW OF THE IMPACT WORKING GROUP ON REGULATORY IMPLEMENTATION

5.1.1 Preamble

Counterfeit medical products pose a significant danger to public health in developing as well as developed countries. Counterfeits may be distributed through different distribution channels such as governmental health systems, hospitals, pharmacies, other legitimate or illegitimate distributors, as well as sold over the internet. Because counterfeiters are good at what they do, licensed distributors, pharmacists, health care providers or patients are sometimes unable to detect or differentiate between counterfeit and genuine medical products. It has been difficult to assess the extent of the problem of counterfeit medical products around the world. Reasons being among others; lack of resources/skills to detect counterfeit medical products, absence or weak regulatory and enforcement systems, different definitions of counterfeit medical products in different countries worldwide, as well as variation in distribution systems. As a result, estimates on the actual extent of the problem may be incomplete and vary from country to country.

5.1.2 Terms of reference

Currently chaired by Dr Ilisa Bernstein, Director, Pharmacy Affairs, Food and Drug Administration, USA

The Working Group aims to:

- promote implementation of Good Manufacturing, Good Distribution and Good Pharmacy Practice guidelines and quality assurance systems to ensure supply chain integrity;
- develop model training materials aimed at improving quality assurance within and supervision of distribution chain;
- develop guidance on the role of quality control laboratories in combating counterfeit drugs;
- develop data collection tools and methodologies to assess national regulatory and enforcement systems in order to identify gaps and measures needed;
- at the request of national authorities develop ad hoc projects to improve capacity to combat counterfeit medicines;
- promote secure exchange of information and alerts among regulatory and/or enforcement officials as appropriate;
- promote networking and collaboration among national drug regulatory authorities;
- develop guidance for pharmacovigilance systems to include reporting and investigating suspected cases of counterfeit medicines.

5.1.3 Main achievements so far

- Led the revision of the WHO Good Distribution Guidelines. Recommendations are made where necessary to strengthen measures to combat infiltration of counterfeit medical products in distribution. Status: WHO

Expert Committee on Specifications of Pharmaceuticals have met and approved the revised guidelines at its 44th meeting in October 2009.

- Developed an assessment tool designed to provide a unified approach of assessing the problem of counterfeit medicines in a particular country, sub-regional or regional setting. Field testing has been carried out in eight countries (Burkina Faso, Cameroon, Mali, Morocco, Niger, Senegal, Uganda and United Republic of Tanzania) so far.
- Developed guidelines for rapid response plan for national drug regulatory authority for signal of suspect counterfeit. This document is intended to provide actions that may be followed by the NMRA in the event of suspect counterfeit medicines in national distribution channels.

5.2 DATA COLLECTION TOOL FOR THE REVIEW OF NATIONAL SITUATIONS CONCERNING COUNTERFEIT MEDICINES

5.2.1 Questions for Interview

This assessment tool is attempting to provide a unified approach of assessing the problem of counterfeit medicines in a particular country, sub-regional or regional setting. The tool addresses existing national legislations on counterfeit medicines, capacity of National Medicines Regulatory Authorities (NMRA) in the control of counterfeit medicines, market control, as well as determining the awareness and efforts of the government and other stakeholders in combating counterfeit medicines. The last part of the tool addresses the issues of collaboration and cooperation among stakeholders at national and international levels.

5.2.2 Legislation

- What are the elements of the current legislation¹ on the control of the manufacture, importation, exportation, distribution, supply and sale of medicines that are essential for combating counterfeit medicines?
- Is there a provision² for the control of counterfeit medicines in the legislation?
- Does the legislation define counterfeit medicines?
- Is the definition consistent with that of WHO?
- How does legislation penalize against criminals of counterfeit medicines?

5.2.3 Capacity of NMRAs

- Provide available statistics on number of cases of counterfeit medicines providing product names and cases prosecuted/convicted/penalties.
- What are the deadlines or performance indicators for investigation/prosecution cases?
- What legal/regulatory measures are actually being used to combat counterfeit medicines?
- What national guidelines/policies are being used for combating counterfeit medicines?
- Provide statistics on inspectors and other officials conducting inspections, sites to be inspected, inspections carried out, etc in the country.
- Provide statistics on training initiatives aimed for inspectors, enforcement officials, judiciary, health professionals and supply chain stakeholders on the techniques for identification, detection, documentation, reporting and communication on counterfeit medicine?
- What procedures or SOPs are used for the following:
 - Managing records, evidence and other information related to individual counterfeit medicines cases.

- Visual inspection and other non-analytical procedures such as determining authenticity for the detection of counterfeit medicines.
- Sampling procedures, including instructions regarding the size of samples, methods of sampling and procedures for sealing samples and submitting to the quality control laboratory for testing.
- Methods and special precautions for isolating and preventing further distribution of suspect counterfeit medicines.
- The system for recording actions taken, including basic tests on suspect counterfeit medicines.
- Methods of seizing and destroying counterfeit medicines, where required.
- Communication of suspected and/or confirmed cases of counterfeit medicines.
- What systems are in place for reporting suspected cases of counterfeit medicines and identifying signals of possible counterfeit cases?
- What system/mechanism is in place to manage conflicts of interest for NMRA staff?

5.2.4 Market control

- Are there designated ports of entry for importation of pharmaceuticals?
 - What measures are being taken to prevent importation through points of entry that are not the designated ones, where applicable?
 - What operational measures are being used to prevent the importation of unauthorized medicines?
- Are there free trade zones for pharmaceutical products in the country?
- What monitoring and enforcement is done in these free trade zones?
- Are there several trade intermediaries for imported medicines? If yes, describe them briefly.
- Are all drug distribution channels licensed or authorized?
 - If yes; what are the licensing criteria for pharmaceutical manufacturers, wholesalers and other distributors, retail pharmacies and other dispensing outlets?
 - What is the percentage distribution of medicines through different distribution channels?
 - Public
 - Private (including Non-Governmental Organization (NGOs))
- What estimated proportion of medicines is sold without original packaging or without proper labelling (wholesaler-wholesaler, wholesaler-retail, retail-patient, any other combination)?
- What is the estimated number of illegal outlets?
- What measures are being taken to control illegal distribution?
- Is there a significant proportion of medicines on the market without a proper marketing authorization?
- Provide available statistics on samples collected and tested for the purposes of detecting counterfeit medicines.
- What measures are in place to manage situations of short supply of medicines?
- What measures are in place to ensure access to medicines where affordability is a problem?

5.2.5 Documentation and reporting mechanism

- Is it mandatory to report any incidents of suspect/detected counterfeit medicines by various stakeholders to NMRA? Tick where appropriate.
 - Pharmaceutical industry
 - Wholesalers
 - Retailers
 - Health professionals and associations
 - Consumers
 - Other government agencies
- Is there a formalized reporting³ mechanism?
Yes () No ()
If yes, describe briefly

5.2.6 Awareness Programmes

- Does your country offer any awareness programmes on medicines counterfeiting? If yes, who is the target audience and how is the effectiveness of the programmes assessed?
- Are confirmed counterfeit cases made public? If yes, how is the information disseminated?

5.2.7 National Collaboration

- Provide information on the national medicines anti-counterfeiting taskforce⁴.
- Describe collaboration with different stakeholders such as manufacturers, wholesalers, retailers etc.

5.2.8 International Collaboration

- Describe any international collaboration in which your country is involved concerning counterfeit medicines.
- Describe examples of information exchange, cooperation in investigating cases and other operational collaboration with different partners at the international level and discuss limitations.
- Include activities involving capacity building and exchange of knowledge, intelligence and experience.

5.2.9 Questionnaire

The objective of this tool is to get a quick overview of the situation concerning counterfeit medicines in a country.

5.2.9.1 Legislative aspects

- The legislation you use to combat counterfeit medicines (CM) is:
 - General legislation on counterfeiting ()
 - Specific legislation on CM ()
 - Pharmaceutical legislation ()
 - Legislation on intellectual property rights ()
-

- Other (specify)
- Do you consider that you need more specific legislation to combat CM in your country?
Yes () No ()
- What is the legal definition of CM in your country?
- What is the operational definition of CM in your country?
- What are the areas where your legislation needs revision?
 - Definition of CM ()
 - Cooperation between national authorities/stakeholders ()
 - Regional cooperation ()
 - International cooperation ()
 - Strengthening the operational capacity of the Medicines Regulatory Authority (MRA) ()
 - Criminalizing the trade of CM ()
 - More severe sanctions for crimes related to CM ()
 - Other (specify)

5.2.9.2 Anticounterfeit actions

- Number/volume of seizures of counterfeit medicines during these years
 - 2006
 - 2007
 - 2008
- For these seizures who was at the origin of the information about the case?
 - MRA: occasionally () often () always ()
 - Police: occasionally () often () always ()
 - Customs: occasionally () often () always ()
 - Health professionals (specify):

..... : occasionally (), often (), always ()

..... : occasionally (), often (), always ()

- Others (specify):
occasionally (), often (), always ()
occasionally(), often(), always()

- What authority carried out the seizure?
 - MRA: occasionally (), often (), always ()
 - Police: occasionally (), often (), always ()
 - Customs: occasionally (), often (), always ()
 - Others (specify):

..... : occasionally (), often (), always ()

..... : occasionally (), often (), always ()

- If there is no seizure during the last three years what are the reasons?

- Absence of CM in the country ()
- Lack of quality testing capacity ()
- Weakness of inspection ()
- Inadequate drug registration system ()
- Insufficient cooperation with Police ()
- Insufficient cooperation with Customs ()
- Other (specify)

- Number of disciplinary, administrative, civil or penal prosecutions initiated

	disciplinary/admn.	civil	penal
2006	less than 5 5 or more	less than 5 5 or more	less than 5 5 or more
2007	less than 5 5 or more	less than 5 5 or more	less than 5 5 or more
2008	less than 5 5 or more	less than 5 5 or more	less than 5 5 or more

- What has been the outcome of prosecutions and administrative action (please choose the statements that best describe the situation)?
 - Administrative/disciplinary sanctions are timely and effectively applied ()
 - Administrative/disciplinary sanctions often difficult to apply ()
 - Number of manufacturers/wholesalers prosecuted or shutdown during the period 2006-2008:
.....
- Number of retailers prosecuted or shutdown during the period 2006-2008:
 - Civil prosecution timely conducted and effective ()
 - Civil prosecution very slow and ineffective ()
 - Penal prosecution timely conducted and effective ()
 - Penal prosecution very slow and ineffective ()
 - Very difficult to obtain information about sanctions ()
 - Cases remain pending for many years ()
 - Other:

5.2.9.3 Sharing information

- Number of CM cases reported during:

	to WHO	to other
2006		
2007		
2008		

- Do you know WHO's Rapid Alert System? Yes: () No: ()
- Number of cases of CM where you informed at least one country of your region:
 - 2006 : officially..... informally.....
 - 2007 : officially..... informally.....
 - 2008 : officially..... informally.....
- Did you identify the origin of the above cases as:
 - National Origin ()
 - International Origin ()
 - Undetermined origin ()
- In the case of an external origin did you contact the MRA of the suspected country of origin?
 - Always ()
 - Sometimes ()
 - Never ()

5.2.9.4 Collaboration with other authorities

- Is there an operational coordination mechanism in your country between
 - MRA-Customs : ()
 - MRA-Police: ()
 - MRA-Police-Customs: ()
 - MRA-Police-Justice : ()
 - Others (Specify):
- Number of joint actions carried out with Police:
 - 2006
 - 2007
 - 2008
- In absence of joint action with Police, what are the main reasons?
 - No cases to act upon ()

- Absence of legal framework ()
 - Absence of tradition of cooperation ()
 - Limited human resources in your department ()
 - Limited human resources in the two departments ()
 - Other:
- Number of joint actions carried out with Customs
 - 2006 :
 - 2007 :
 - 2008 :
- In absence of joint actions with Customs, what are the main reasons?
 - No cases to act upon ()
 - Absence of legal framework ()
 - Absence of tradition of cooperation ()
 - Limited human resources in your department ()
 - Limited human resources in the two departments ()
 - Other:.....
- Number cases you could not investigate because of lack of coordination with:
 - Police :
 - Customs :
- Does Customs services systematically require MRA permit before releasing medicines at ports of entry?
 - For private sector Yes () No ()
 - For public sector Yes () No ()
 - For NGOs Yes () No ()
- Number of permits issued by MRA in 2007:
 - For private sector
 - For public sector
 - For NGO
- Number of counterfeit cases handled by courts in
 - 2006 :
 - 2007 :
 - 2008 :

- In these cases did the court ask for input from
 - MRA ()
 - Other MOH experts
 - Health professionals (specify)
 - others

- Number of meetings on counterfeit medicines with Police, Customs and other stakeholders during:
 - 2006:
 - 2007:
 - 2008 :

5.2.9.5 MRA and WHO initiatives

- Do you know that IMPACT recommends the designation of a SPOC (Single Point of Contact) in each country to coordinate the fight against CM?
Yes No

- Did your government designate a SPOC in your country?
Yes No
If yes, provide SPOC details:

- Did your country participate in IMPACT meetings in?
 - 2006 :
 - 2007 :
 - 2008 :

5.2.9.6 Free trade zones in your country

- Are there free trade zones in your country?
Yes No

- Is the trade on medicines in these zones oriented to:
 - Your local market
 - Only export
 - Export and local market

- Are these free trade zones under the supervision of the MRA?
Yes No Yes but difficult to supervise
Specify issues of concern: Is the National Pharmaceutical Legislation applicable in the free trade zones:
Yes No

If no specify what legislation is applicable (customs, trade):

- What kind of inspections are conducted in the free trade zones:
Pharmaceutical () Customs () Other (specify):

- How many pharmaceutical inspections were conducted in the free trade zones in
 - 2006 :
 - 2007 :
 - 2008 :

5.2.9.7 Market control

- Number of medicinal products authorized for marketing in your country
(same marketing authorization number =same product):
number date

- Number of authorized medicinal products estimated to be actually on the market:
number date

- Number samples collected in market surveys in 2007 from
 - Public sector
 - Private sector

- Number of samples analysed in 2007 from
 - Public sector
 - Private sector

- Is there an informal market for medicines in your country?
Yes () No ()

- What is the relative importance of this informal market?
 - Very marginal ()
 - Important (some of the population depend on it for their medicines supply) ()
 - Very Important (large population depend on it for their medicines supply) ()
 - Limited to some areas of the country ()
 - Limited to rural areas ()
 - Limited to some metropolitan areas ()
 - Widespread ()

- Number of raids conducted in the informal market

	NRA alone	NRA and police	other arrangement
2006			
2007			
2008			

- Additional information/remarks or problem not covered by the questionnaire:

5.2.10 Notes

¹Focus on identifying gaps and limitations and issues of coordination between different institutions.

²Focus on identifying gaps/limitations and if there are prohibitions against counterfeit products, packaging and related activities?

³Linkage with other vigilance systems

⁴For example, public list of cases, press releases, public alerts

⁵Mention participating stakeholders, legal basis, plans and resources, etc.

⁶For all the questions you can check multiple answers. Feel free to add comments to further clarify the information you are providing.







6

**WORKING GROUP
ON TECHNOLOGY**

6.1 OVERVIEW OF THE IMPACT WORKING GROUP ON TECHNOLOGY

6.1.1 Preamble

There are many anti-counterfeit technologies available to manufacturers and brand owners, ranging from the very simple but effective to the highly sophisticated and extremely secure. The majority can be implemented on one or more of the packaging components, but some features can even be applied at the product level.

The purpose of an anti-counterfeit feature is primarily to enable the authentication of an item. The second function may be to act as a deterrent to anyone considering counterfeiting a product based on the difficulty or cost involved set against the likelihood of detection, and therefore prosecution. It must be stressed that anti-counterfeit features on packaging components provide no assurance as to the authenticity of the contents, which may have been substituted or adulterated. They can also be subject to imitation and counterfeiting attempts. Anti-counterfeit features alone do not reduce counterfeits, but are on the one hand designed to make them easier to detect and on the other hand increase the hurdle for potential counterfeits. They are most effective when used as part of a holistic approach.

6.1.2 Terms of reference

Currently chaired by Mr Eduardo Pisani, Director General, International Federation of Pharmaceutical Manufacturers and Associations. The Working Group aims to:

- assess (including piloting when feasible and necessary) technologies to prevent, deter, or help to detect counterfeit products taking into account: a) cost, b) scalability, c) specific country needs and situations, d) feasibility, e) regulatory implications;
- facilitate exchange of information on technologies and their implementation
- disseminate information and recommendations on the merits and limitations of technologies

6.1.3 Main achievements so far

- Developed a guide on “Anti-counterfeit Technologies for the Protection of Medicines” for IMPACT. This document assesses existing technologies to prevent, deter or help to detect counterfeit medicinal products. A new chapter is being developed, to include anti-tampering technologies.
- Two meetings of regulators to discuss anti-counterfeiting technologies, exchange experiences and learn about new developments in the field (Prague, 2007 and Singapore, 2008) [see 1.4].
- Recommendations to the Enforcement WG on simple ways to fast track authentication of suspect counterfeit pharmaceuticals products.
- Development (ongoing) of a comparative analysis of different field testing devices, with respect to:
 - needs of different user groups (i.e. regulators, rights holders);
 - needs in different locations and
 - critical success factors.

6.2 ANTI-COUNTERFEIT TECHNOLOGIES FOR THE PROTECTION OF MEDICINES

This document was kindly prepared by Mr. G. Power, on behalf of the IFPMA, and benefited from input by the IMPACT members. Document presented by the Technology working group and approved at the second General Meeting of IMPACT, Lisbon, 2007.

6.2.1 Introduction

There are a great many anti-counterfeit technologies available to manufacturers and brand owners, ranging from the very simple but effective, through to the highly sophisticated and extremely secure. The majority can be implemented on one or more of the packaging components, but some features can even be applied at the product level, either by direct marking or by using physical or chemical markers within the formulation.

The purpose of an anti-counterfeit feature is primarily to enable the authentication of an item, by government, industry investigators, or ideally, by the wider public. The second function may be to act as a deterrent to anyone considering counterfeiting a product based on the difficulty or cost involved set against the likelihood of detection, and therefore prosecution. It must be stressed that security devices on packaging components provide no assurance as to the authenticity of the contents, which may have been substituted or adulterated. Security devices alone do not reduce counterfeits, but are designed to make them easier to detect.

Anti-counterfeit technologies can be broadly classified as follows:

- Overt, or visible features
- Covert, or hidden markers
- Forensic techniques
- Serialisation/Track and Trace

This paper will consider each of these 4 categories, whilst avoiding specific reference to any licensed product or provider. However, it must be recognised that some of these technologies are protected by international patents, and may only be available from licensed suppliers, subject to appropriate royalties or license fees. On the other hand, some can be applied in-house, with little expenditure on materials and effort, and most are available from reputable suppliers, some of whom specialise in security applications.

Note: *the following comments and conclusions must be viewed as very general to each group of technologies, and inevitably there will be exceptions with, and omission of, some more specialist applications.*

6.2.2 Anti-counterfeit technologies

6.2.2.1 Overt (Visible) Features

Overt features are intended to enable end users to verify the authenticity of a pack. Such features will normally be prominently visible, and difficult or expensive to reproduce. It should be noted that overt features can add significant cost, may restrict supply availability, and require education of end users to be effective. Where overt features are used, experience is often that counterfeiters will apply a simple copy which mimics the genuine device, sufficiently well to confuse the average user. They also require utmost security in supply, handling and disposal procedures to avoid unauthorised diversion. They should be applied in such a way that they cannot be reused or removed without being defaced or causing damage to the pack – otherwise genuine used components may be recycled with fake contents, giving a false impression of authenticity. For this reason an overt device might be incorporated within a Tamper Evident feature for added security.

Holograms

Probably the most familiar overt feature is the “dove” hologram which has been used to protect credit cards for many years. A hologram normally incorporates an image with some illusion of 3-dimensional construction, or of apparent depth and special separation.

Holograms and similar optically variable devices (OVD) can be made more effective when incorporated in a tamper evident feature, or as an integral part of the primary pack (e.g. blister foil). They can be incorporated into tear bands in overwrap films, or as threads embedded into paper substrates.

However, some hologram labels have been easily and expertly copied or simulated, and may often rely on hidden covert elements for authentication.

Optically Variable Devices (OVD)

OVDs also include a wide range of alternative devices, similar to holograms, but often without any 3D component. Generally they involve image flips or transitions, often including colour transformations or monochromatic contrasts. Like holograms, they are generally made up of a transparent film which serves as the image carrier, plus a reflective backing layer which is normally a very thin layer of aluminium. Other metals such as copper may be used to give a characteristic hue for specialist security applications.

Extra security may be added by the process of partial de-metallization, whereby some of the reflective layer is chemically removed to give an intricate outline to the image, as can be seen on many banknotes. Alternatively the reflective layer can be so thin as to be transparent, resulting in a clear film with more of a ghost reflective image visible under certain angles of viewing and illumination. Partial removal of the metallic layer is a more restricted process and thereby increases both the level of security and the cost.

Colour shifting security inks and films

These can show positive changes in colour according to the angle viewing angle, and can be effective either as an overt graphic element or by incorporation in a security seal.

Colour shifting pigments are finely ground metallic laminates which need to be laid down in a thick opaque film to

achieve the optical effect, and are therefore better suited to printing techniques such as gravure and screen printing rather than lithographic printing. Their security value lies in the specificity and dynamics of the colour change (e.g. from blue to gold), combined with the difficulty and expense involved in manufacture. They are only available from a limited number of pigment suppliers, via a few specialist ink manufacturers. Positive authentication may involve forensic (microscopic) examination and embedded taggants.

Colour shifting films have been used for security applications, involving multi-layer deposition of thin films to build up a structure with unique diffractive properties, and vibrant colour transitions. They can be applied as security seals or tamper evident labels.

Security graphics

Fine line colour printing, similar to banknote printing, incorporating a range of overt and covert design elements such as guilloches, line modulation and line emboss. They may be used as background in a discrete zone such as an overprint area, or as complete pack graphics, and can be printed by normal offset lithography, or for increased security by intaglio printing. Subtle use of pastel “spot” colours makes the design more difficult to scan and reproduce, and security is further enhanced by the incorporation of a range of covert design elements, such as microtext and latent images.

Sequential product numbering

Unique sequential numbering of each pack or label in a batch can make counterfeits easier to detect in the supply chain. If printed visibly, it provides a semi-overt means of authentication by reference to a secure database, because duplicates or invalid numbers will be rejected. The main disadvantages of sequential numbering are that the sequence is predictable and easily replicated, and end users require some means of access to the database. The more secure option is serialisation by means of a pseudo-random non-repeating sequence, and this is discussed in the Track and Trace section.

On-product Marking

On-product marking technologies allow for special images or codes to be placed on conventional oral dosage forms. These overt technologies can be difficult to replicate and offer a security technology at the pill level. This added layer of security is effective even when products are separated from the original package.

General Conclusions: Overt features represent an attempt to put authentication into the hands of the general public. However, to be effective they demand public education and awareness, which is especially difficult in the most challenged developing markets. It should also be noted that the more widely used one overt security technology becomes, the more attractive it is for counterfeiters to defeat it

General conclusions

OVERT FEATURES

Advantages	Disadvantages
User verifiable	Require user education - not always widely understood
Newer technologies more secure	May be easily mimicked
Can add decorative appeal	May add significant cost
Can be a deterrent to counterfeiters	May rely on covert features for authentication
	May be re-used or refilled
	May give false assurance

Overt features represent an attempt to put authentication into the hands of the general public. However, to be effective they demand public education and awareness, which is especially difficult in the most challenged developing markets. It should also be noted that the more widely used one overt security technology becomes, the more attractive it is for counterfeiters to defeat it.

6.2.3 Covert (Hidden) Features

The purpose of a covert feature is to enable the brand owner to identify counterfeited product. The general public will not be aware of its presence nor have the means to verify it. A covert feature should not be easy to detect or copy without specialist knowledge, and their details must be controlled on a “need to know” basis. If compromised or publicised, most covert features will lose some if not all of their security value. For this reason such techniques will not be disclosed in detail in this paper.

Examples include:

Invisible Printing

Using special inks, invisible markings can be printed on almost any substrate, and which only appear under certain conditions, such as via UV or IR illumination. They can be formulated to show different colours with illumination at different wavelengths.

Embedded Image

An invisible image can be embedded within the pack graphics which can only be viewed using a special filter, and cannot be reproduced by normal scanning means. The effects can be quite dramatic, and yet well hidden.

Digital Watermarks

Invisible data can be digitally encoded within graphics elements and verified by means of a reader and special softw-

re. The data can be captured using webcam, mobile phone or other scanning equipment, but the digital information is not visible to the human eye, and attempts to replicate it will be detected by virtue of the degradation of the embedded data.

Hidden Marks and Printing

Special marks and print may be applied in such a way that escapes attention and is not easy to copy. Their effectiveness relies on a combination of secrecy and subtlety, and hence no further details will be discussed here.

Anti-copy or Anti-scan design

Fine line background patterns appear as uniform tones, but when scanned or copied reveal a latent image which was not previously visible. Commonly used on secure documents to prevent photocopying, they may be applied to product packaging as a background tint.

Laser Coding

The application of batch variable details by lasers coding requires special and expensive equipment, and results in recognisable artefacts which may be difficult to simulate. Laser codes can be applied to cartons and labels, and plastic and metal components.

Substrates

There are many ways of incorporating covert markers within a substrate, such as visible or UV fluorescing fibres, or chemical reagents in carton board or paper. Watermarks can be embedded in leaflet paper, or metallic threads interwoven in the base material, possibly including an overt OVD feature. These require a dedicated supply source and large volume production, which, if affordable, results in a very effective option.

Odour

Micro-encapsulated distinctive odours can be applied as an additive to an ink or coating to provide a novel covert or semi-overt feature.

General conclusions

COVERT FEATURES

Advantages	Disadvantages
Can be simple and low cost to implement	Need strict secrecy—"need to know"
Needs to regulatory approval	If widely know or used, may be easy to copy
Can be easily added to or modified	More secure options add supply complexity and cost
Can be applied in-house or via component suppliers	If applied at component suppliers, greater risk of compromise

Covert features are most effective in the hands of industry specialists. They are a very valuable investigative tool, but a counterfeiter will be able to copy many of the simpler features unless they are skilfully applied and their details are kept secret. However, there is almost unlimited scope to the possibilities, given imagination and ingenuity on the part of the technologist and designer, and the costs can be minimised or even eliminated when applied in-house. In-house application also has advantages of limiting involvement of third party suppliers, who may not be trustworthy in some environments. Only the most secure covert features can be safely used in an overt context, and these generally come under the next heading of forensic markers.

6.2.4 FORENSIC Markers

There is a wide range of high-technology solutions which require laboratory testing or dedicated field test kits to scientifically prove authenticity. These are strictly a sub-set of covert technologies, but the difference lies in the scientific methodology required for authentication.

Examples include:

Chemical taggants

Trace chemicals which can only be detected by highly specific reagent systems, but not normally detectable by conventional analysis.

Biological taggants

A biological marker can be incorporated at extremely low levels (parts per million or lower) in product formulations or coatings, or invisibly applied to packaging components. At such low levels they are undetectable by normal analytical methods, and require highly specific “lock and key” reagent kits to authenticate.

DNA taggants

Highly specific DNA “lock and key” reagent systems can be applied to packaging by a variety of printing methods. They require a “mirror image” recombinant strand to effect the pairing, and this reaction is detectable by a dedicated device. Security is further assured by hiding the marker and reagent pair in a matrix of random DNA strands, but the test is tuned to work only with one recombinant pair.

Isotope ratios

Naturally occurring isotopes can be highly characteristic of the source of a compound, and accurately determined by laser fluorescence or magnetic resonance techniques. These can provide a “fingerprint” of one or more of the product constituents, or alternatively a specific marker can be added with its own unique signature. Detection requires highly specialist laboratory equipment

Micro-taggants

Micro-taggants are microscopic particles containing coded information to uniquely identify each variant by examination under a microscope. This may take the form of alphanumeric data depicted on small flakes or threads, or of fragments of multicoloured multilayered laminates with a signature colour combination. These can be embedded into adhesives, or directly applied to packaging components as spots or threads.

General conclusions

FORENSIC TECHNOLOGY

Advantages	Disadvantages
High tech and secure against copying	Licensed technologies
Provide positive authentication	Significant cost
May be disclosed for overt purposes	May be difficult to implement and control across many markets
	Wider use increases risk of compromise
	Unlikely to be available to authorities or public

There are some very robust and secure options available, which may enable their use to be more widely known and therefore accessible to trusted authorities and investigators. However, these tend to be subject to patent protection and therefore restricted in availability and pricing.

6.2.5 Serialisation/TRACK and TRACE Technologies

A number of Track and Trace applications are under development for the pharmaceutical sector, although the principles have been established for many years in other contexts. These involve assigning a unique identity to each stock unit during manufacture, which then remains with it through the supply chain until its consumption. This identity will normally include details of the product name and strength, and the lot number and expiry date – although in principle it may simply take the form of a unique pack coding which enables access to the same information held on a secure database. (This latter solution overcomes some of the concerns about privacy where the encoded data can be read at a distance by radio equipment.)

These serve a number of distinct functions:

- Tracking an item through the supply chain, to each point where there is the facility for data capture.
- Providing traceability on the history of any item (electronic pedigree), subject to limitation of number of control points.
- Enable authentication of the data at any time, and by implication, of the pack or unit on which it is applied.

The most obvious benefits are in the supply logistics, where greater transparency of inventories and demand patterns can lead to efficiency improvements and cost reductions. Another benefit is the ability to identify a product through to dispensing to the patient, enabling the elimination of medication errors and the ability to speedily recall defective product batches. But the ability to tightly control and authenticate all product through the supply chain greatly reduces the possibilities for counterfeit, stolen or diverted product entering the distribution system without being detected.

It should also be noted that Track and Trace tags or labels may not necessarily be applied at the unit pack level, but

may be restricted to whole cases or even pallets – thereby affording the logistics benefits but not all the safety and security gains. As has been mentioned before, a key security element lies in pack serialisation.

Serialisation

In itself the Track and Trace label may not be immune to copying or falsification, but its security is greatly enhanced by the inclusion of unique and apparently random serialisation, or non-sequential numbering, ideally at individual item level. If the serialisation was sequential, then the level of security would be very low as the sequence is predictable, whereas “random” serialisation using a highly secure algorithm or method of encryption overcomes this. Individual packs may still be copied, but the database will identify duplicates or invalid serials, as well as those which have been cancelled or expired, or which appear in the wrong market, or with invalid product details.

Where secure serialisation is applied visibly to a pack, then it may be authenticated by customers via a telephone or internet link to the database. One issue to be resolved is ownership, management of and access to the database, to ensure that the information is readily accessible and yet secure against compromise.

There are two main vehicles for the incorporation of unique pack data in order to facilitate automatic data capture:

Bar Codes

These are high-density linear or 2 dimensional bar codes incorporating product identity down to unit pack level, which are scanned and referenced to the central database. One popular implementation is the 2D datamatrix code, and other possibilities include PDF417 codes. A 2D code can typically be 1cm square or smaller, and yet contains up to 1 Kb of data with some “redundancy” or error correction. Where space is not a limitation, linear bar codes may also be used. The codes are printable by on-line methods including inkjet or digital printing, allowing direct computer control and transfer of records to the central database. Hierarchical systems are developed whereby the label on a shipping case is inextricably linked to the identities of all its contents, and this can further extend up the chain to pallet labels, thereby overcoming the necessity for line of site scanning through the supply chain.

So-called “nano-printing” technologies allow microscopic application onto individual tablets. UV inks allow invisible printing onto any substrate including glass vials and ampoules.

Radio Frequency Identity (RFID) Tagging

An RFID tag comprises of an antenna with a microchip at its centre. This contains item-specific and batch information which can be interrogated at a distance, and without requiring line of sight (unlike bar codes). The radio frequency used determines the range and sensitivity, but no one specification suits all applications. Some systems are able to capture multiple records for a mixture of different products, but there are some issues around orientation of the tags and absorbance of the radio signal by liquids and foils. But one clear advantage of RFID is that it has the potential to be fully automated in warehouses and even through to pharmacies, without requiring manual intervention.

Specifications for equipment and data standards are being developed. The cost of tags remains a significant barrier to individual pack application, as does the availability of the application and verification equipment if it is to be implemented to pharmacy level. Robustness of the tags during application and handling through to end of life is another issue, as trials to date indicate a significant failure rate. However there is optimism that a printed version may be

developed. Privacy issues, and susceptibility to deliberate adulteration must also be addressed prior to widespread implementation.

Unique surface marking or topography

There are several methods for applying a pseudo-random image to each item in a batch, such as a pattern of lines or dots in one area of the carton, and then scanning the signature into the batch database via secure algorithms, for later authentication. Alternatively, the pack surface provides a unique fingerprint when scanned by a dedicated laser device, which enables each pack to be registered into the database at batch manufacture, and which is impossible to replicate or falsify.

General conclusions

SERIALISATION | TRACK AND TRACE

Advantages	Disadvantages
High tech and secure against copying	Significant cost to implement and monitor
May be capable of remote authentication, via phone or Internet	Difficult to implement across multiple markets
May be accessible to authorities and investigators without compromise	May be vulnerable to hackers
May eliminate dispensing errors	Damaged labels may not read
Facilitates recall of defective product	Robustness of RFID tags not proven
May combat theft and fraud	Needs harmonisation to the public
Benefits in supply efficiencies	Not accessible to the public
	Remote reading causes privacy issue

Unique pack serialisation has the potential to deliver robust solutions to fraud and counterfeiting of pharmaceuticals, but is not yet fully developed. Barcode systems use proven existing technology, but lack the advantage of automation and remote scanning possible with RFID. But RFID systems are not yet proven or robust, and standards need to be agreed and defined. RFID tags may be vulnerable to deliberate and invisible alteration or corruption.

6.2.6 Summary and conclusions

As can be seen above, there is a huge range of possible solutions ranging from the very simple to the highly complex, from zero cost to highly expensive and from fragile to highly secure against compromise. The wide range of options adds to the potential security by diluting the advantage gained by a counterfeiter in defeating any one system, and manufacturers should choose widely and wisely for optimum security gain.

It is unlikely that any one solution will be appropriate for all applications - the costs may not be affordable in developing markets, or for low margin products including generics and OTCs.

Pharmaceutical manufacture is not restricted to highly developed and sophisticated societies, but is almost universal. Therefore, not all areas share the same accessibility to technological solutions, and their supply infrastructure. It is also noted that reliable and secure sources of supply may be wanting in some regions where there is a poor history of intellectual property protection. Manufacturers may be confined to using only in-house technologies in such territories.

Virtually all of the available solutions carry some cost and administrative burden, whereas the manufacturers' business case for cost versus benefits is extremely difficult to quantify. This is not helped by many unsubstantiated claims for the level of counterfeits in the global medicines market. The true business case is more realistically based on risk management and corporate ethical responsibility for public health and safety, except in those few areas where the counterfeit level is measurable.

Finally, there is no single solution to every problem, and a secure strategy will almost certainly involve a mixture of technologies, often in combination. An overt feature will almost certainly include a secure covert element for added security, and any one product may carry several different features on various levels of the pack and components. But as long as counterfeiters target medicines for illegal profit, a product with no form of anti-counterfeit marker represents a significant potential risk to public health and safety.

Overt user-verifiable solutions would be the ideal option, if only they were universally robust, affordable and readily understood by end users. Some licensed technologies claim to achieve this, but mandating the use of these would be counter-productive. They may not be suitable for all applications, nor affordable by all manufacturers for all products, and their wider use would become a greater incentive to counterfeiters to invest in engineering the technology, as has happened with holograms.

Recommendation: overt features should only be used at the discretion of manufacturers. Their use should be encouraged where products and/or markets are known to be at risk, and where used, manufacturers should educate the public (including wholesalers, distributors and healthcare professionals) in the means by which they can be authenticated. There is little purpose in mandating the use of an overt solution, as counterfeiters will be obligated to attempt to defeat or to circumvent it.

Covert solutions have much to offer manufacturers, but offer little benefit to authorities and the general public because of the risk of compromise if widely known or widely used. However, they can be very cost beneficial and relatively simple to manage.

Recommendation: Manufacturers should be encouraged to apply covert markers across their entire range of products and markets, to provide a basic means of monitoring the situation. Wide use of one or two simple features should be

discouraged however, as the risk of compromise increases for all, and they should not be relied upon alone to solve an ongoing problem of counterfeiting. Manufacturers should consider sharing knowledge of some covert markers with trusted supply chain partners.

Forensic markers have some advantages over the simpler covert features, but generally at a cost premium, both in terms of licensing fees or royalties and the equipment required. Their security may be sufficiently robust to allow overt advertisement of their presence, and they may bridge the gap between less secure covert features and unreliable overt features.

Recommendation: the use of forensic markers should be encouraged in areas of high risk, and once a manufacturer has committed to a system there may be advantage in wider use across their portfolio for little extra cost. However, choice of system must be at manufacturers' discretion and any attempt to mandate a solution must be discouraged.

Serialisation/Track and Trace systems differ by not necessarily being secured against copying, but by protecting the supply chain against infiltration and abuse. They also have additional benefits of safety, and the improvements in supply logistics and efficiency suggest that they may be self financing before even taking into account safety issues and counterfeit elimination. There is good reason to believe that a common database structure will support any of the proposed implementations, whether 2D barcode or RFID. RFID shows promise, but there is a long way to go before it is proven, reliable, affordable and practical in all markets. It should also be recognised that the problem of counterfeiting is greatest in markets where the IT infrastructure needed to support Track and Trace is most lacking, and the traders in counterfeits have no incentive to encourage its development.

Recommendation: manufacturers and healthcare providers should be encouraged to the platforms, standards for and practicalities of implementing Track and Trace technology. Establishment of specifications for the data structure and database infrastructure are essential platforms to harmonisation of a universal system. Principles of ownership, management and access must be agreed, and the modes of access made as flexible as possible. The choice of hardware platform should be left to manufacturers, but it is recommended that for speed and economy a barcode based system should be developed as a priority, allowing natural progression to RFID if, when and where feasible. RFID tagging may be more effective at pallet and case level, but 2D barcodes more affordable at individual pack level. An industry wide working group should be established to define the standards, with representation from government, branded and generics manufacturers, wholesalers, distributors, pharmacists and healthcare practitioners. Consideration should be given to how access might be afforded to authorities such as customs, police and public health investigators, as well as ultimately to the customer.



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Counterfeit medical products are a major public health risk for all communities.

Responding to the growing public health crisis of counterfeit drugs, in February 2006, the World Health Organization launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), a partnership comprised of all the major anti-counterfeiting players, including international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturers associations and drug and regulatory authorities.

IMPACT THE HANDBOOK

IMPACT provides the opportunity to discuss matters which fall within the Terms of Reference and, where appropriate, to formulate proposals and recommendations to be adopted through a consensus-based approach and made public. Such proposals and recommendations and working plans do not commit the participating governments, organisations, institutions, agencies and associations in any way, but constitute a reference for guidelines, official policy or other action, as appropriate.

This handbook resumes the activities and the history of the task-force, through the documents published since the 2006 “Declaration of Rome”: terms of reference, Q&A on the IMPACT activities, and a summary of working papers by each Working Group.

The publication also includes a CD-ROM with the promotional videos and the graphic materials developed by IMPACT, and the files of the enclosed documents.

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